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(54) **CERVIX MONITORING SYSTEM AND RELATED DEVICES AND METHODS**

(76) Inventors: **Hebah Noshy Mansour**, La Mirada, CA (US); **Ramez Emile Necola Shehada**, La Mirada, CA (US)

Correspondence Address:
**CHRISTIE, PARKER & HALE, LLP**
**PO BOX 7068**
**PASADENA, CA 91109-7068 (US)**

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(22) Filed: **Aug. 30, 2004**

**Related U.S. Application Data**

(60) Provisional application No. 60/498,496, filed on Aug. 28, 2003. Provisional application No. 60/576,479, filed on Jun. 2, 2004. Provisional application No. 60/587,530, filed on Jul. 13, 2004.

**Publication Classification**

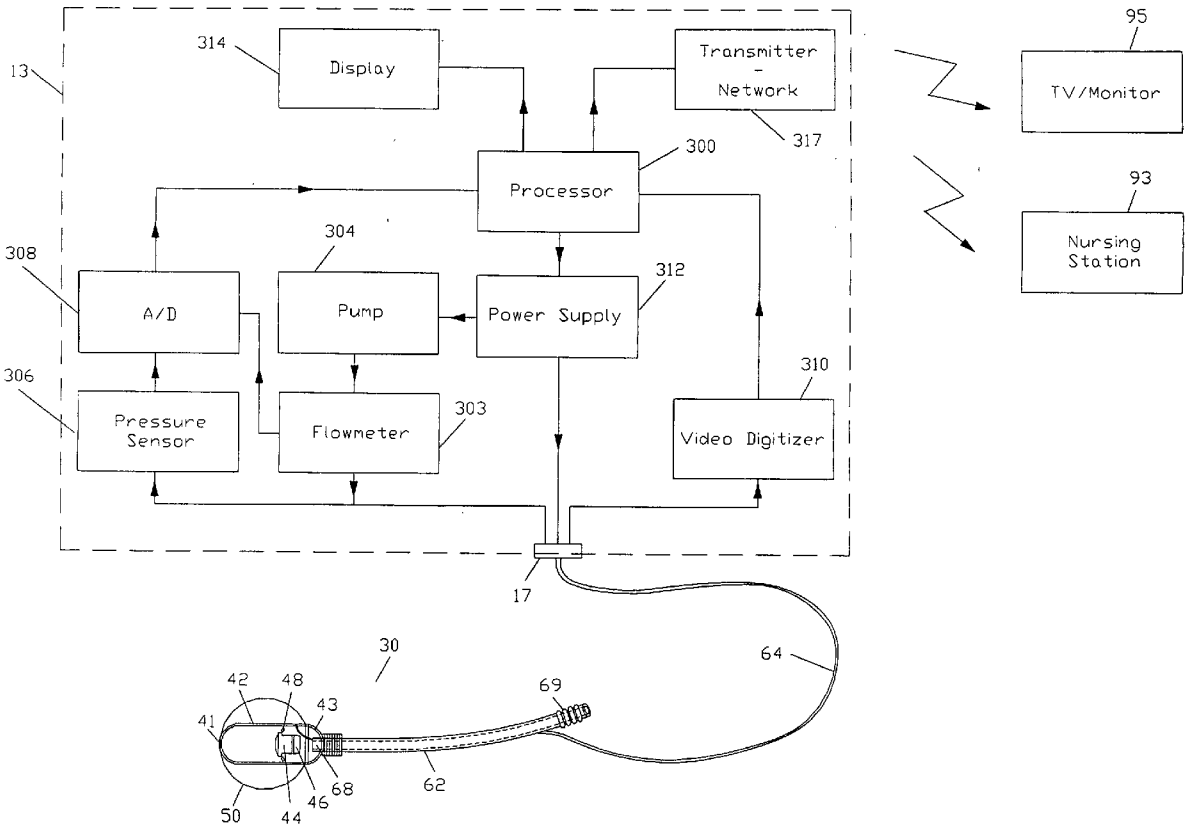
(51) **Int. Cl.**[7] ..... **A61B 5/00**; A61B 5/103

(52) **U.S. Cl.** ..... **600/476**; 600/591

(57) **ABSTRACT**

The present invention is directed to a minimally invasive system and method for monitoring changes in a cervix opening during labor, including changes in its diameter. The system having a probe and a monitoring unit serve to monitor periodically the cervix opening during labor and obtain measurements of the diameter of the cervix opening. The probe primarily includes a camera for imaging the cervix opening, a lens to provide an optimal field of view for the camera at close range to the cervix opening, a light source to illuminate the cervix and a balloon to expand the vagina around the probe and position the probe to allow unobstructed imaging of the cervix.

The monitoring unit which controls the probe to acquire images of the cervix and receives and processes image data from the probe includes a processor which uses image segmentation techniques to identify and measure the opening of the cervix and generates data signals. The monitoring unit also includes an image display which displays information based on the data signals for viewing by health care providers and/or the patient, including graphic images of the cervix opening and other text information relating to the cervix opening as an indicator of the progress of labor. In one embodiment, the processor implements segmentation techniques and/or blob analysis algorithms to analyze the images of the cervix to identify the opening and measure its diameter. Other algorithms may also be implemented to correct for any spatial distortion, particularly barrel distortion.



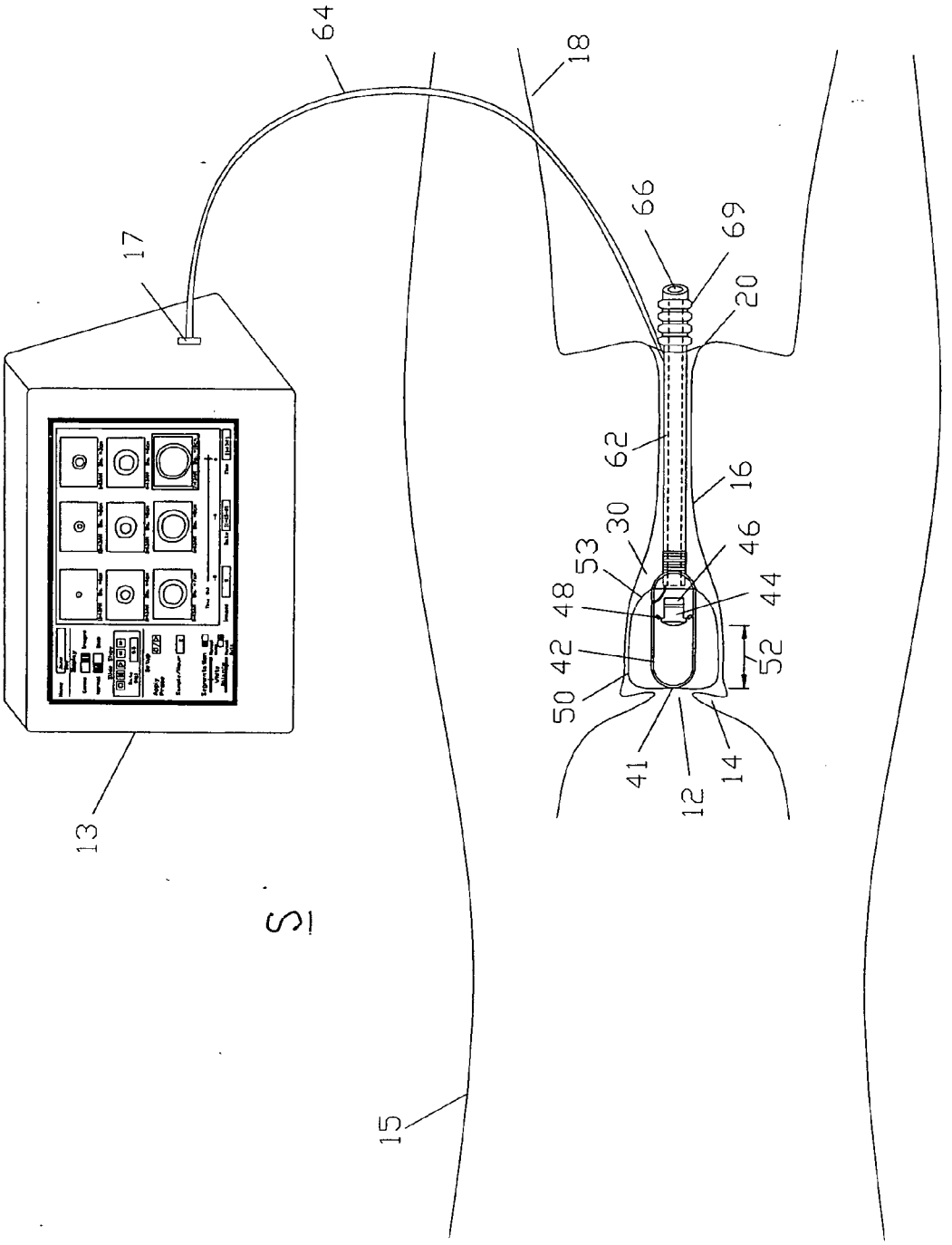



FIG. 1

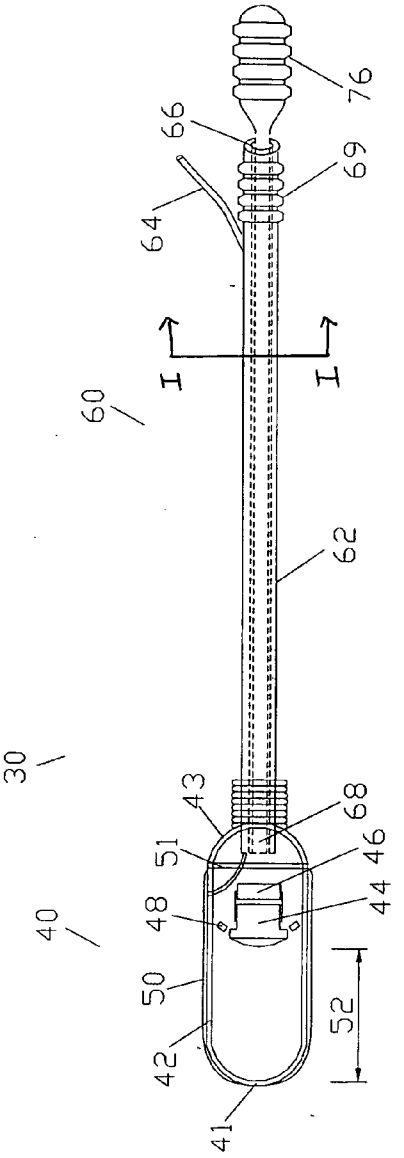



FIG. 2B

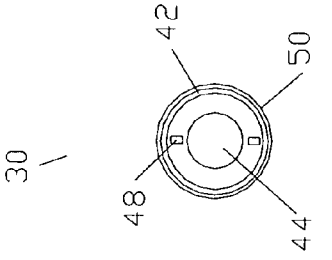



FIG. 2A

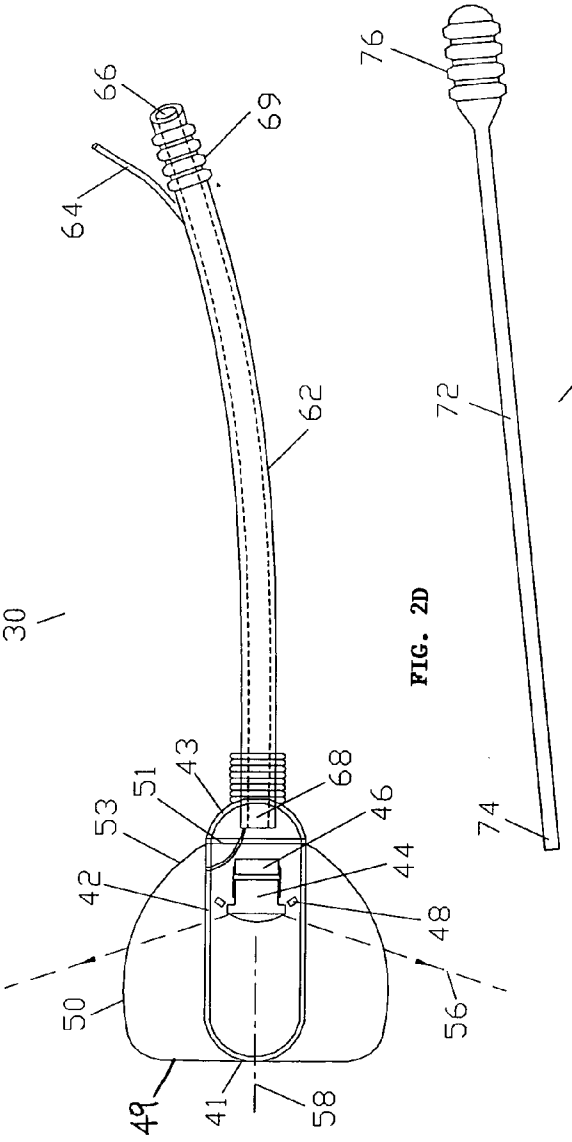



FIG. 2D

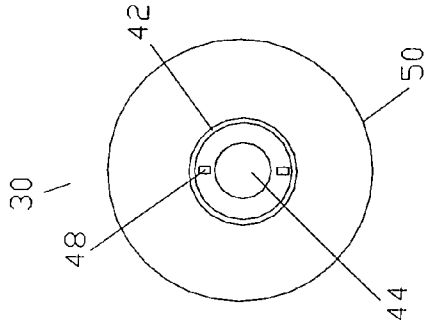



FIG. 2C




FIG. 2E

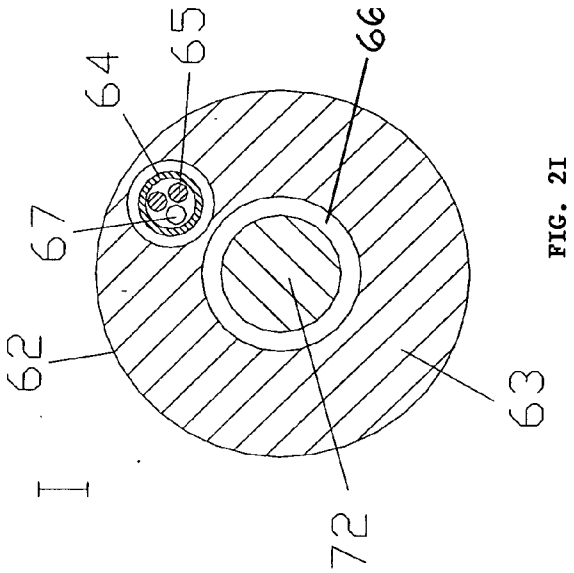



FIG. 2I

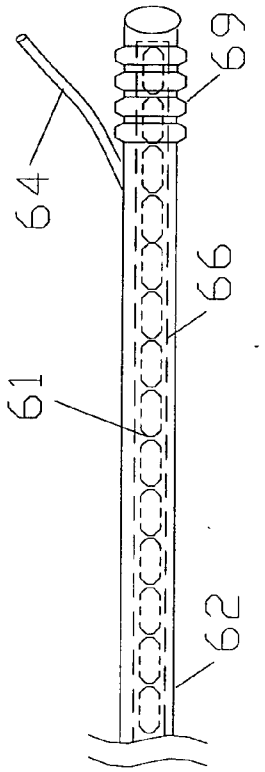



FIG. 2F

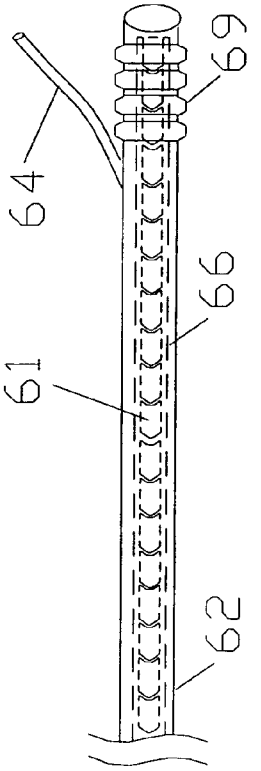



FIG. 2G

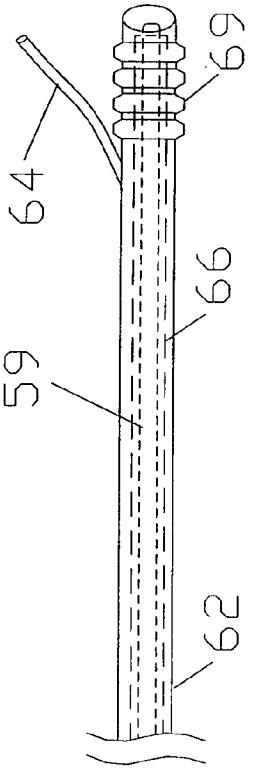



FIG. 2H

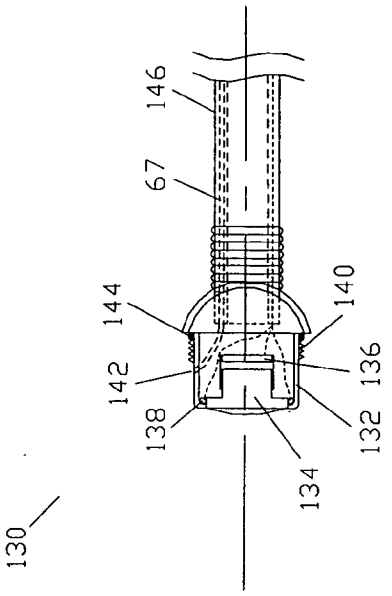



FIG. 3B

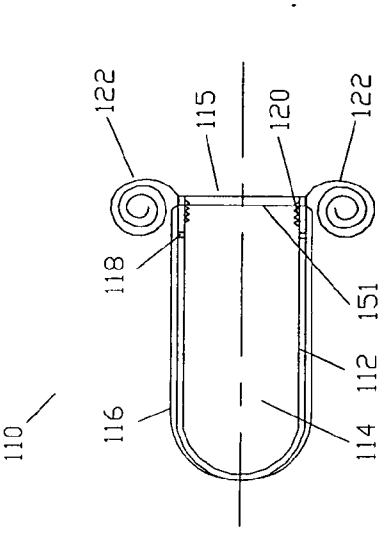



FIG. 3A

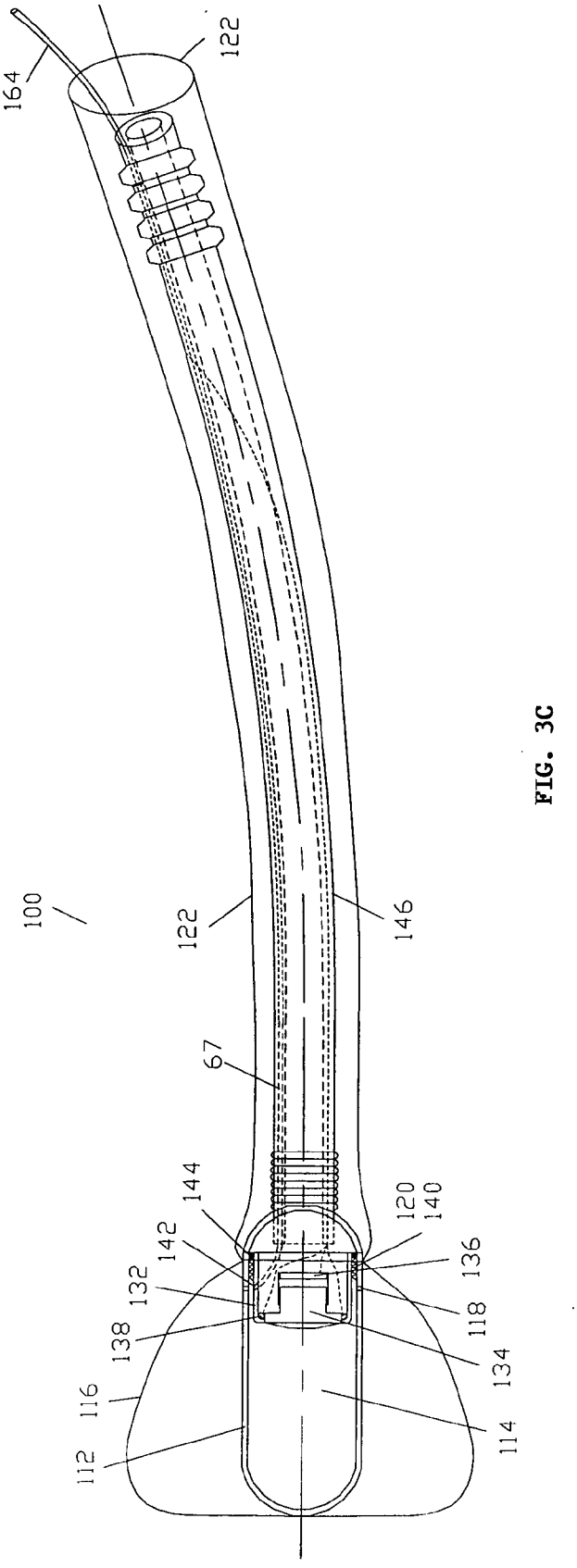
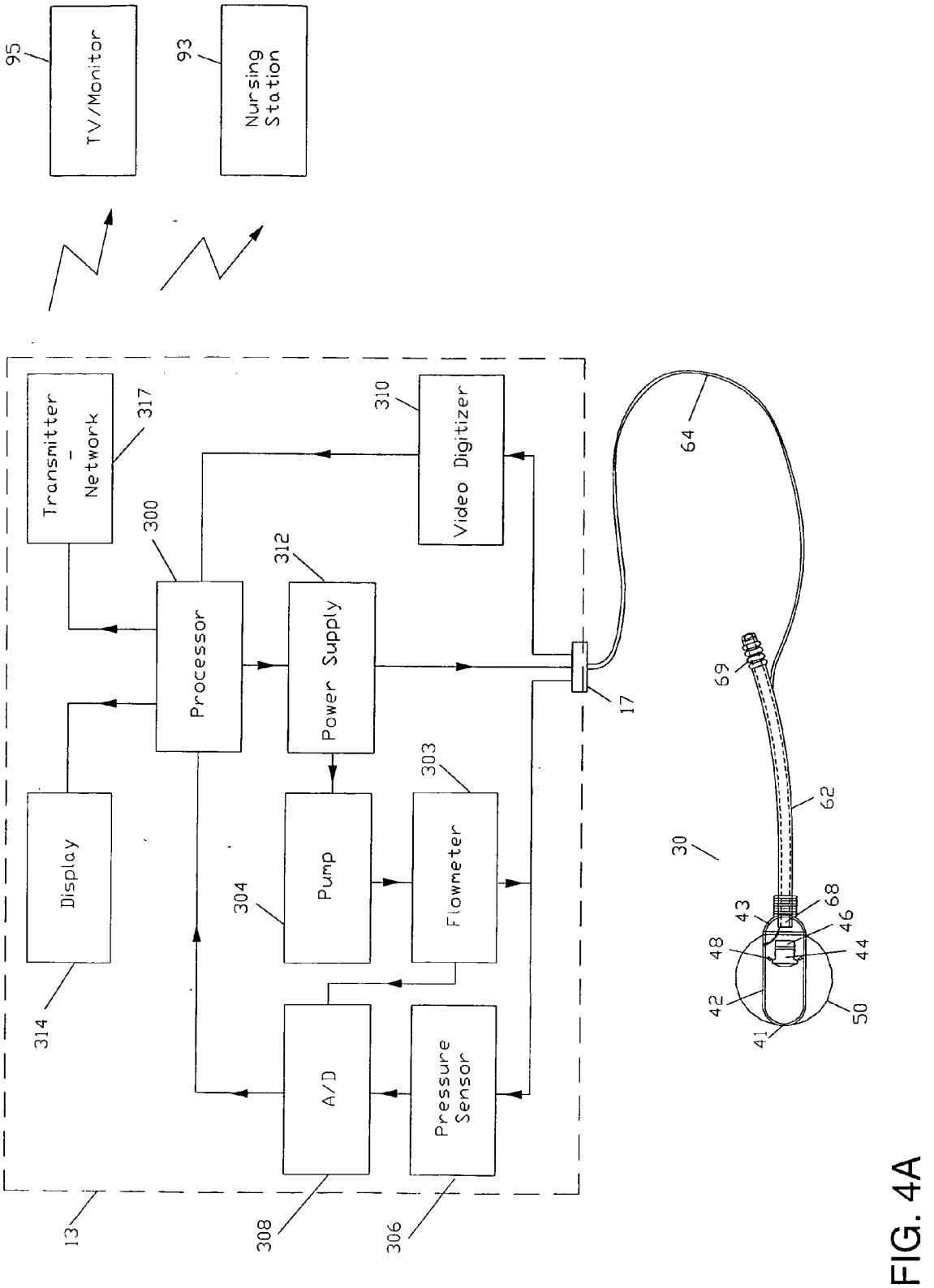



FIG. 3C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Nursing Station
Transmitter - Network
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Video Digitizer
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Processor
Power Supply
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Display
Pump
Flowmeter
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A/D
Pressure Sensor
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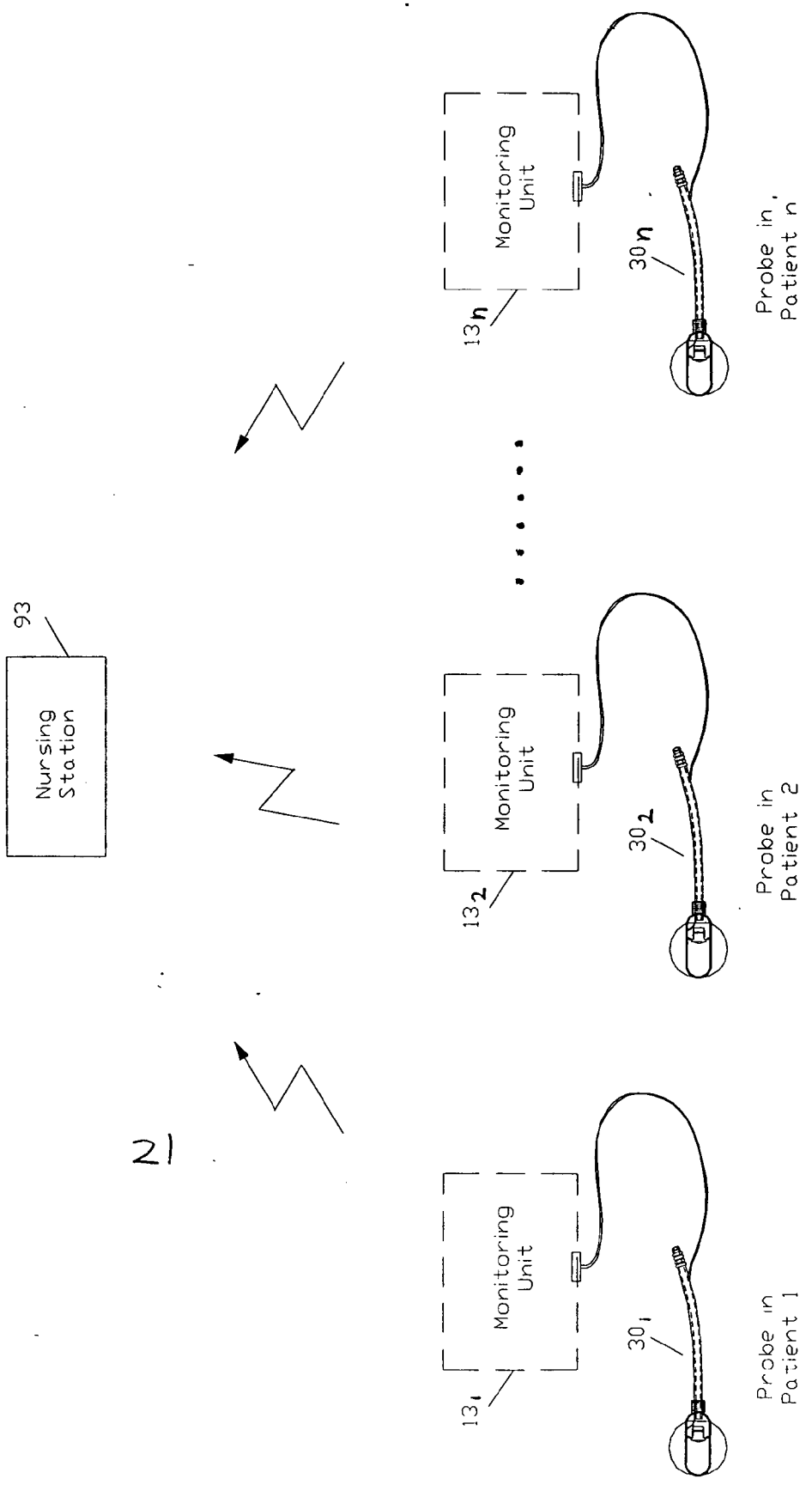
308
306

FIG. 4A


93
Nursing Station
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Monitoring Unit
$13_1$
$30_1$
Probe in Patient 1
Monitoring Unit
$13_2$
$30_2$
Probe in Patient 2
Monitoring Unit
$13_n$
$30_n$
Probe in Patient n

FIG. 4B

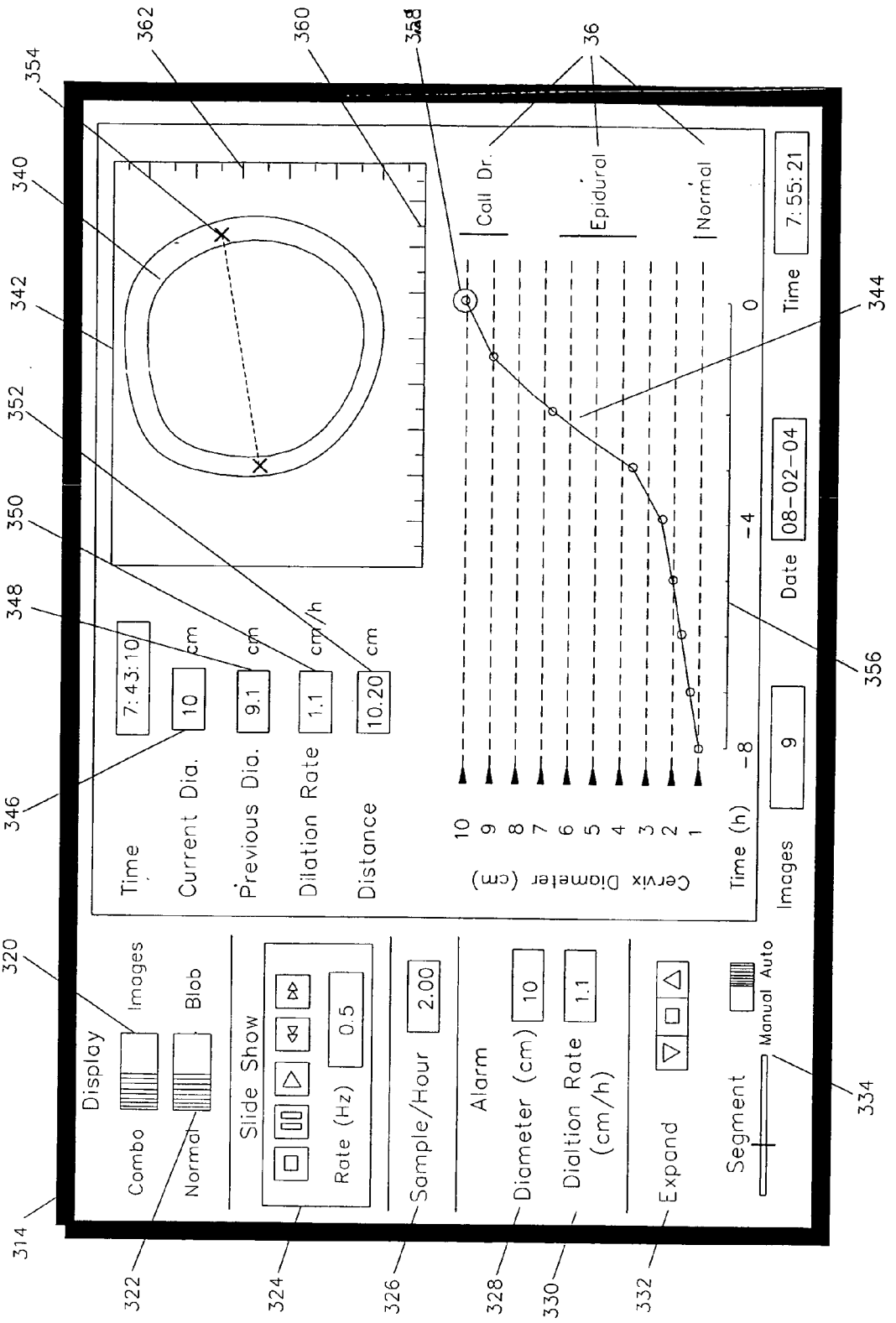
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FIG. 5a

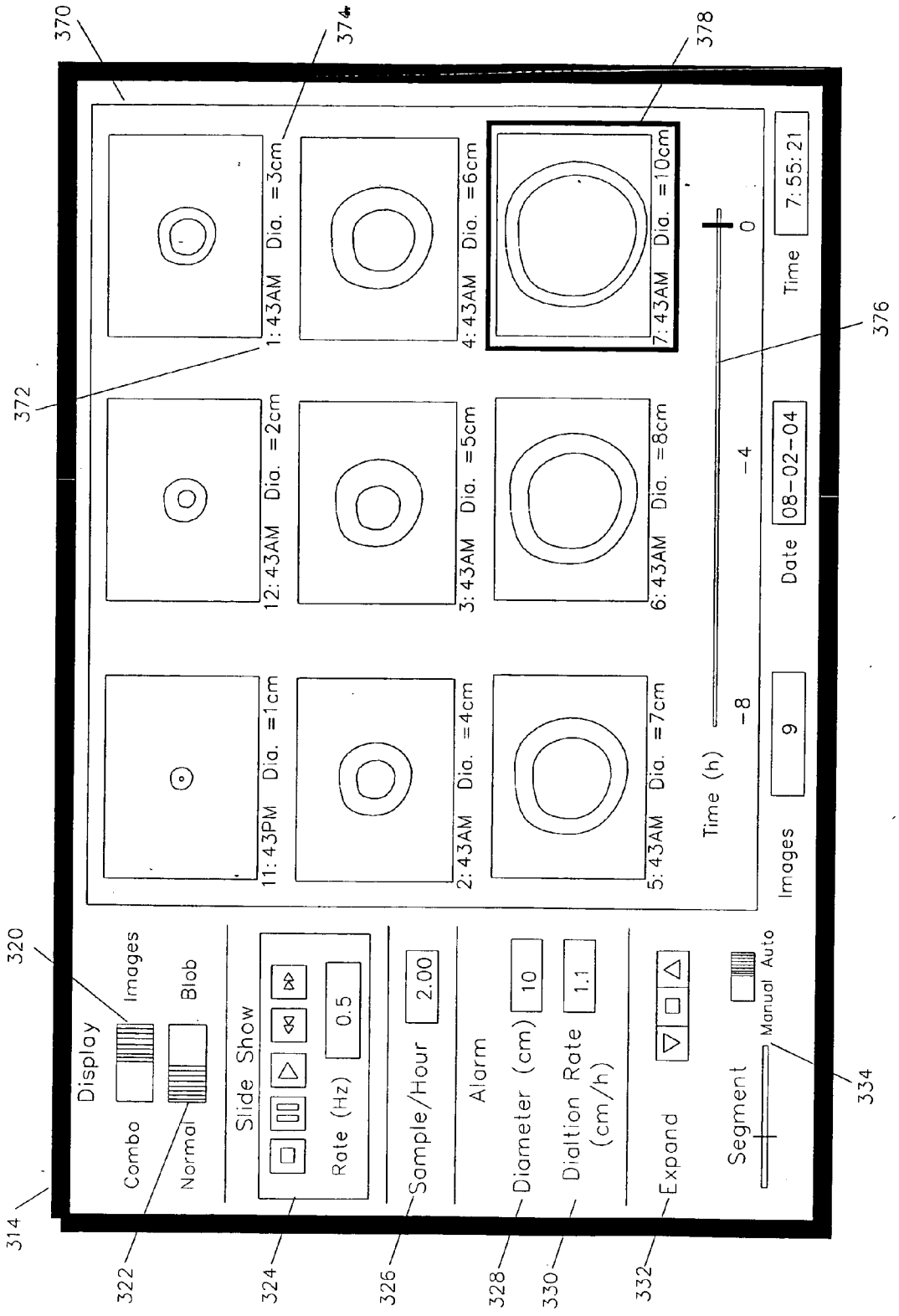
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FIG. 5b

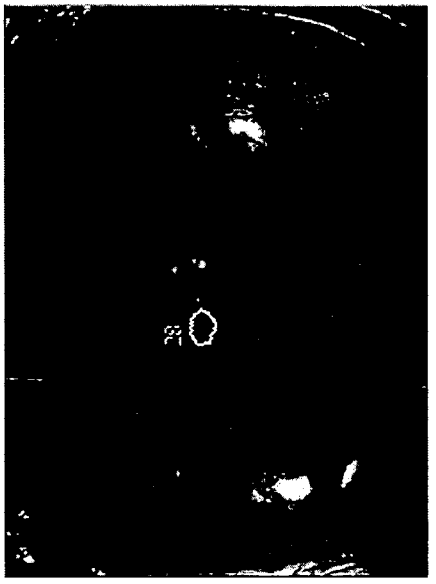

FIG. 6C

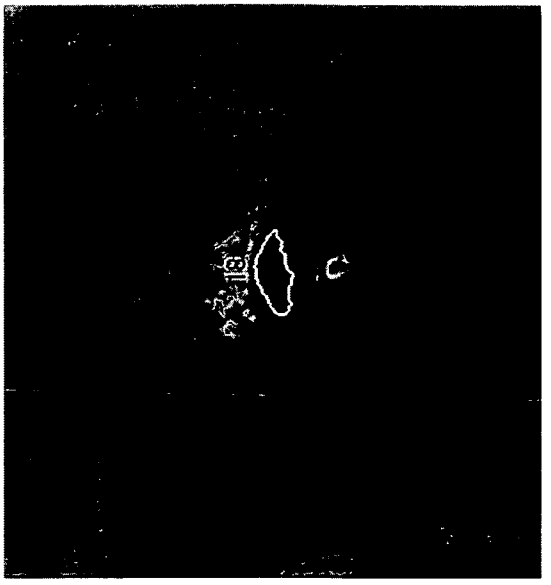

FIG. 6D


FIG. 6A

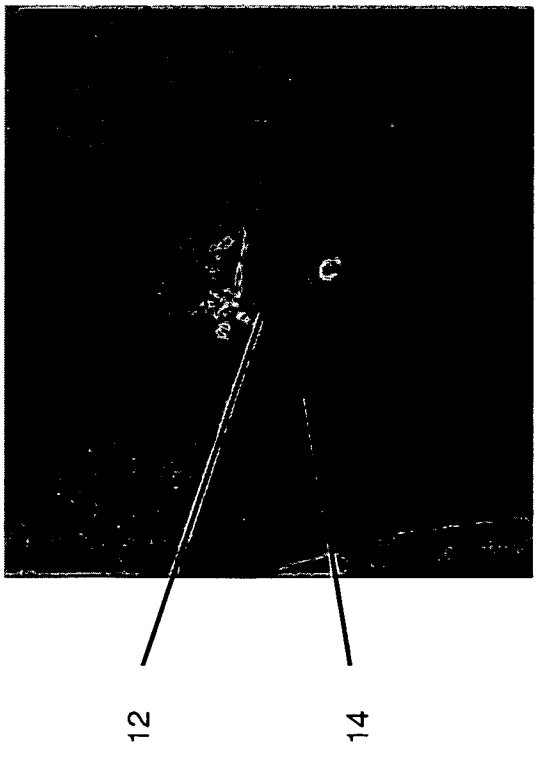


FIG. 6B

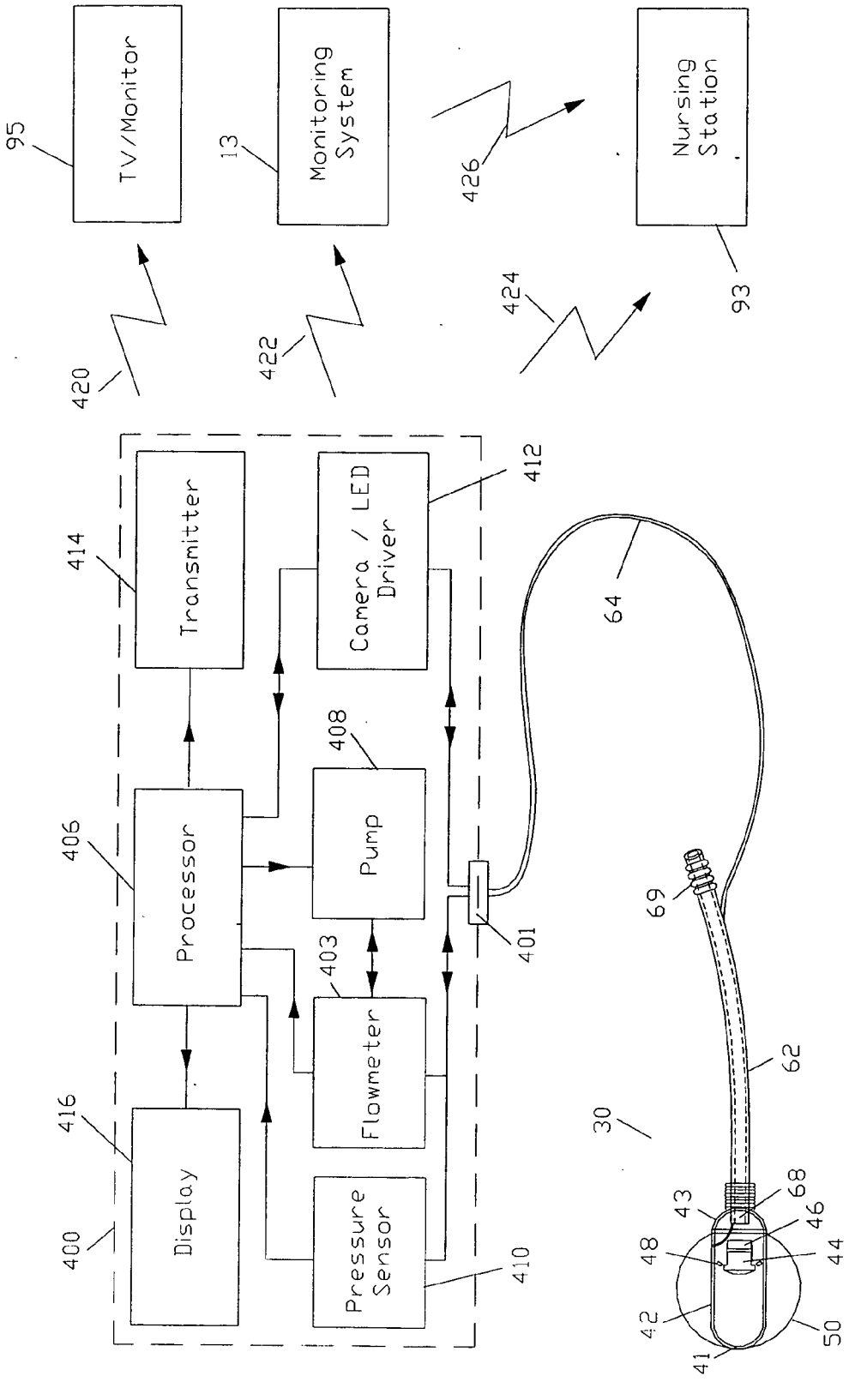
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FIG. 7

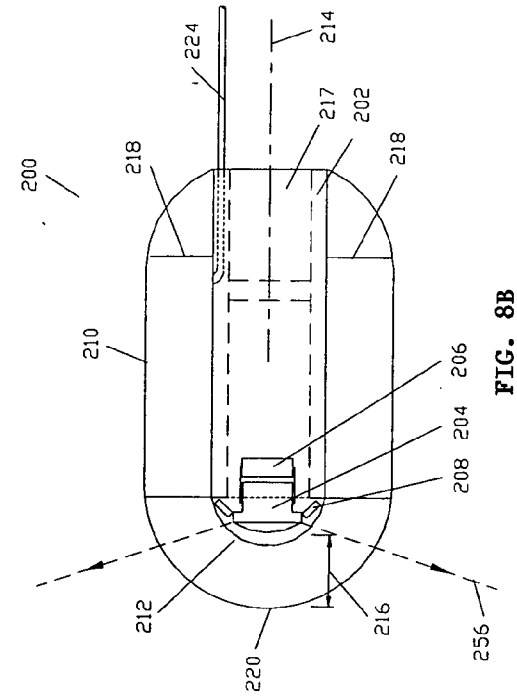


FIG. 8B

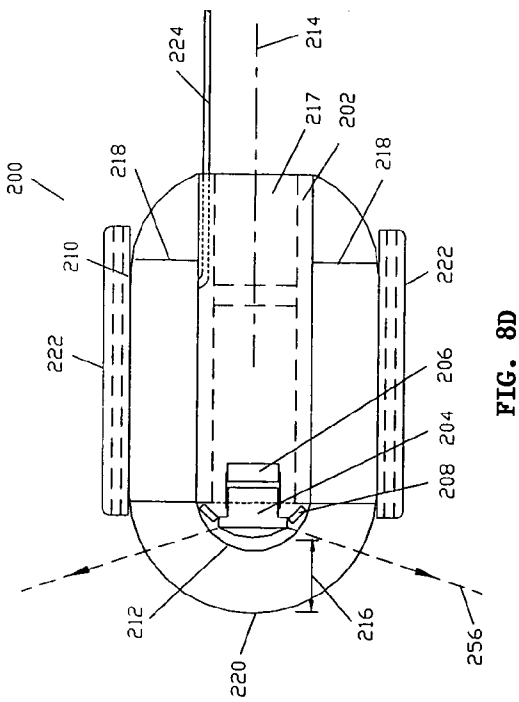


FIG. 8D

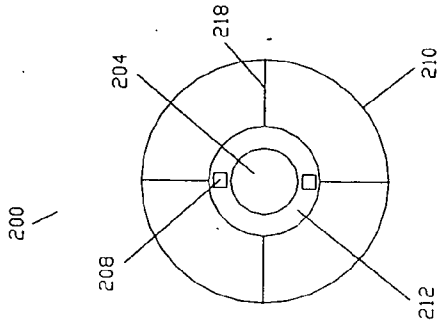


FIG. 8A

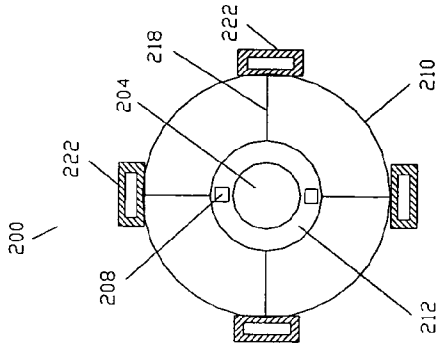


FIG. 8C

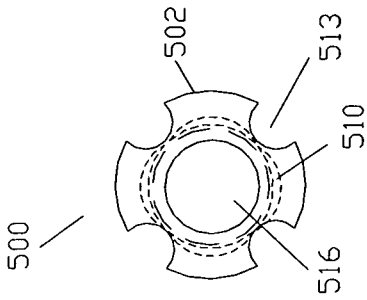


FIG. 9C

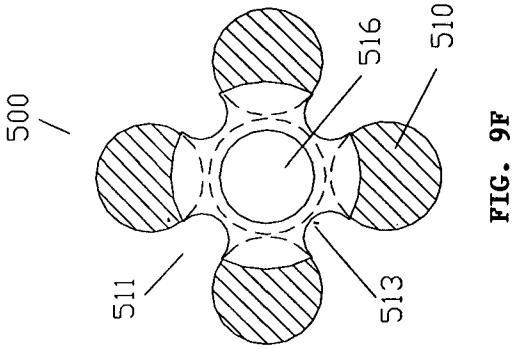


FIG. 9F

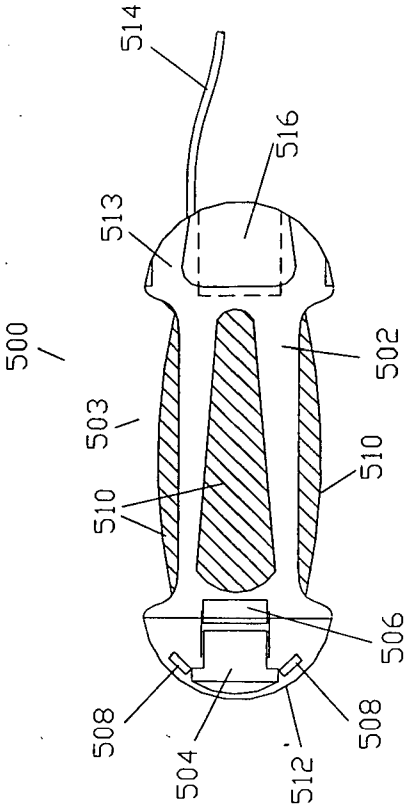


FIG. 9B

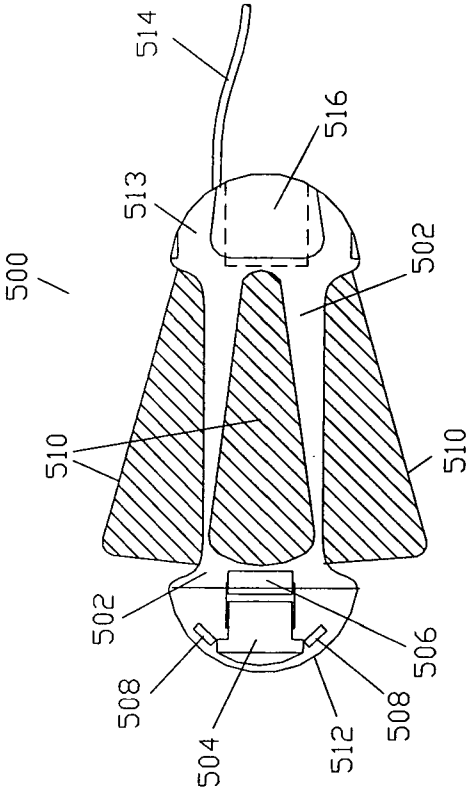


FIG. 9E

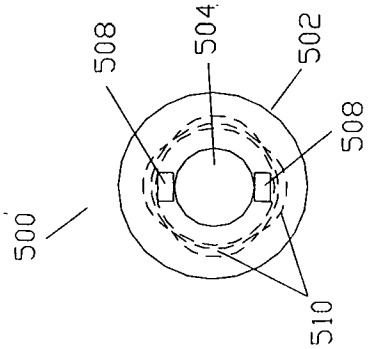


FIG. 9A

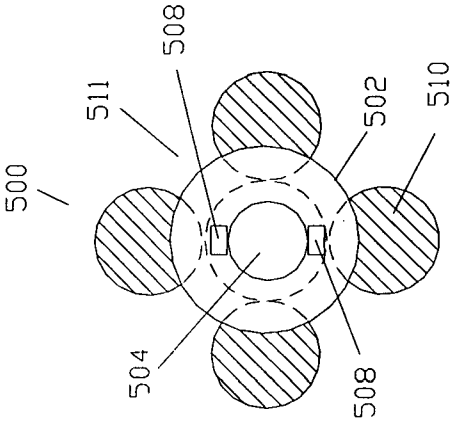


FIG. 9D

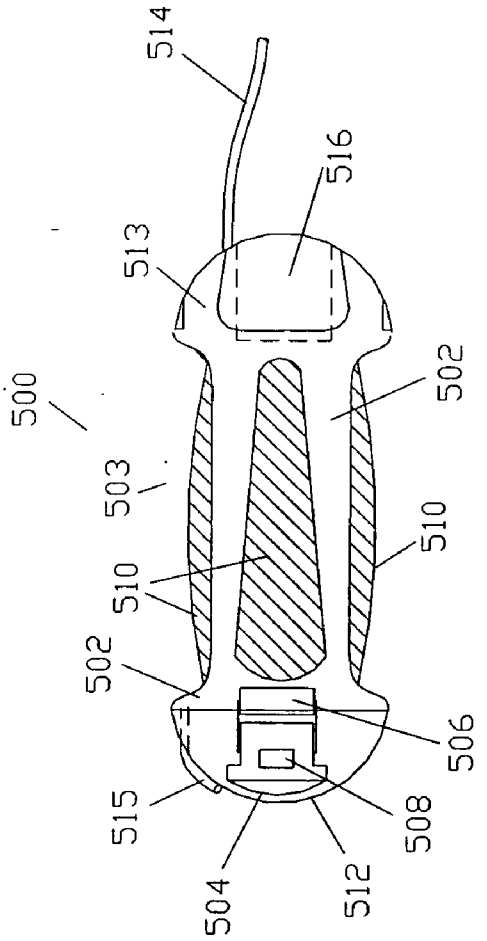
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FIG. 9H

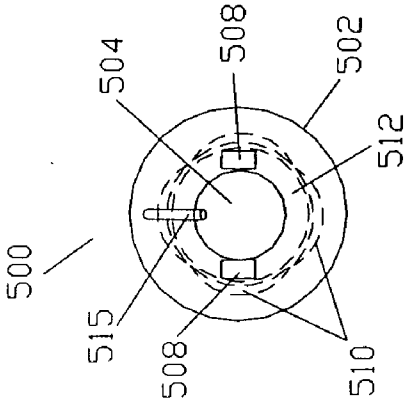
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FIG. 9G

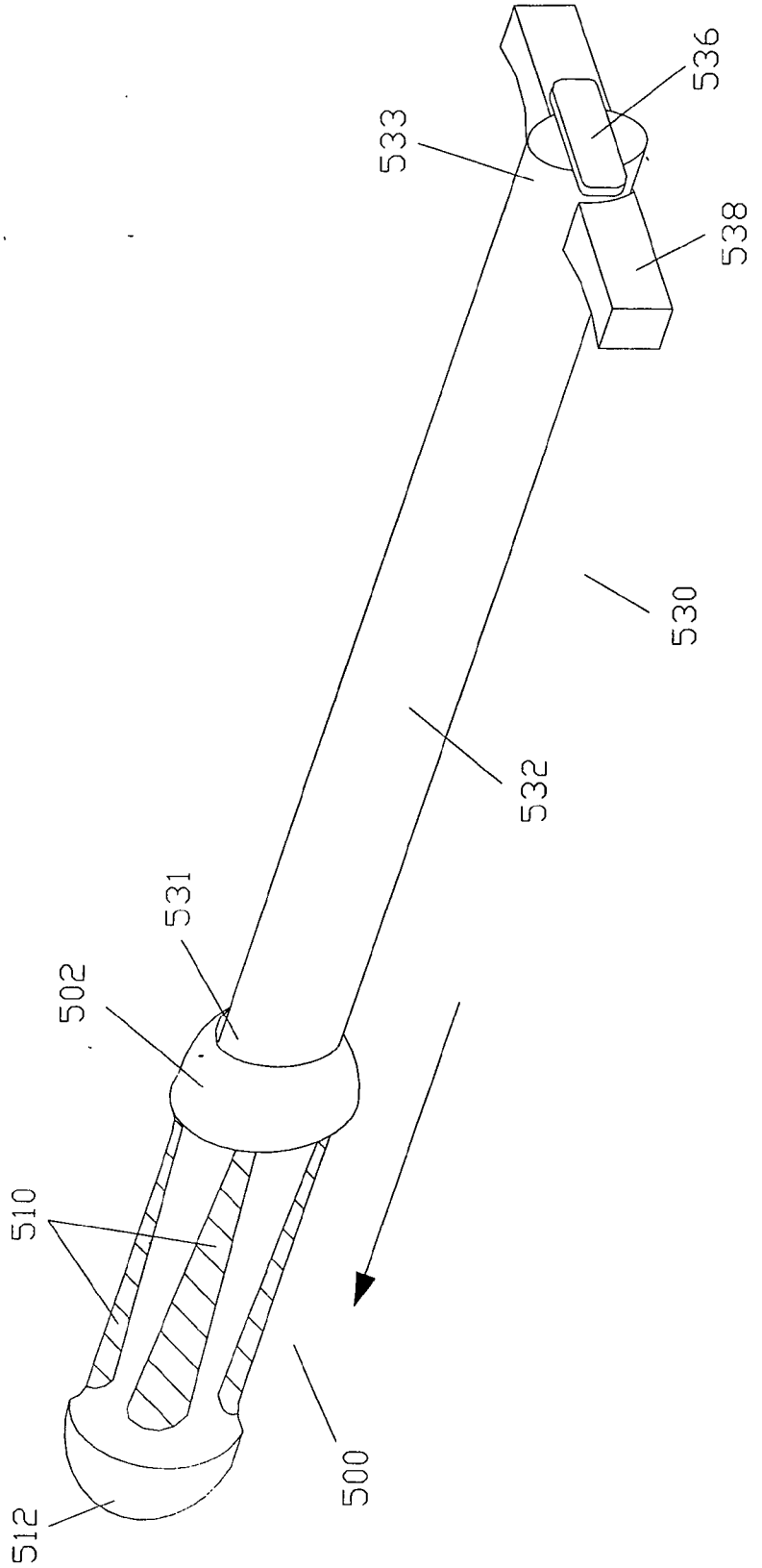


FIG. 10

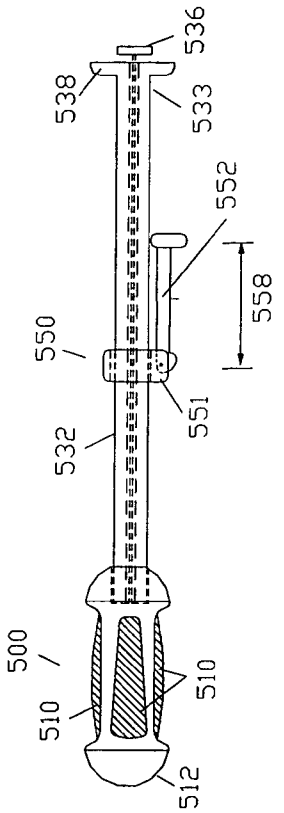


FIG. 11B

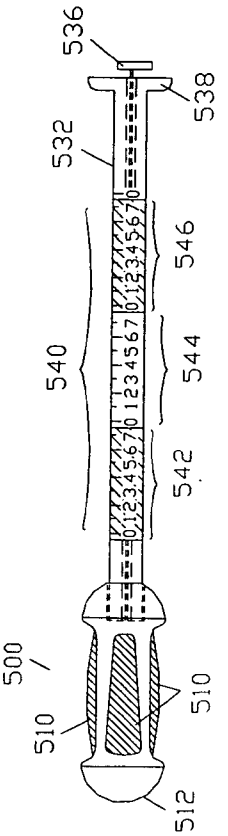


FIG. 11A

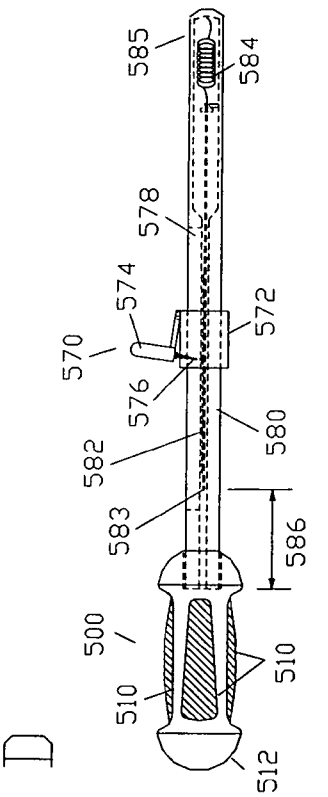


FIG. 11D

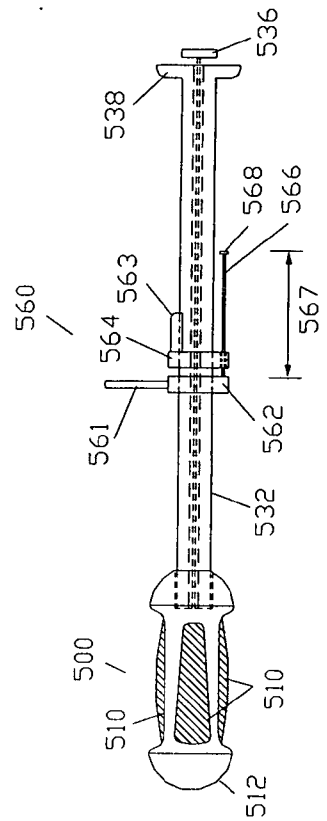


FIG. 11C

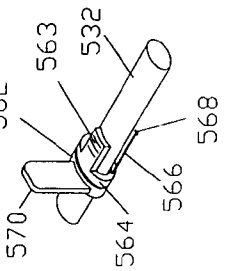


FIG. 11E

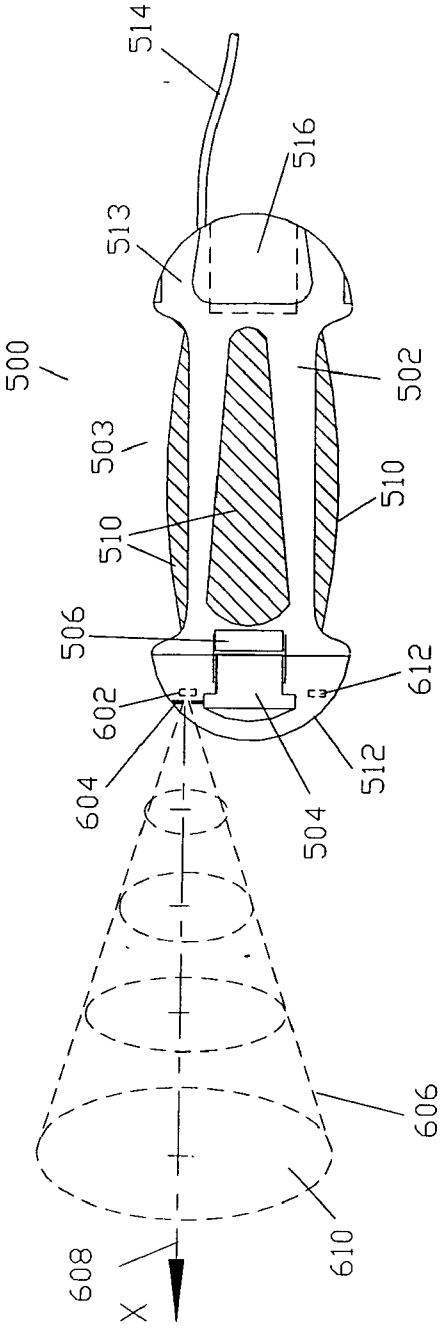


FIG. 12A

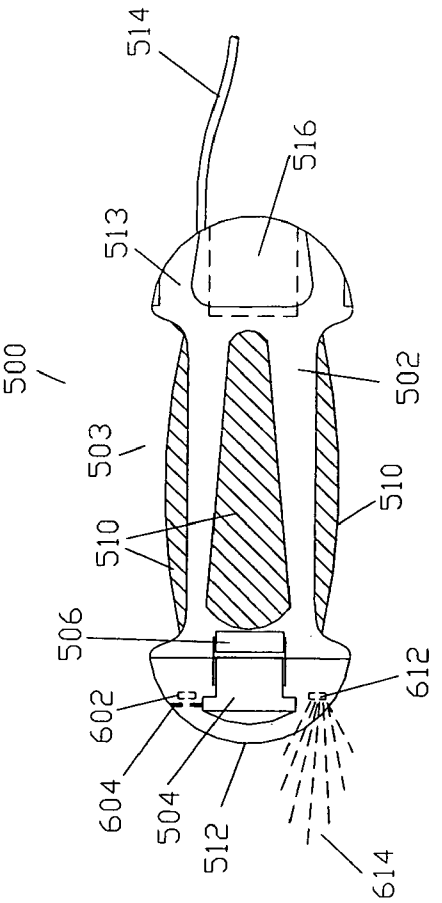


FIG. 12B

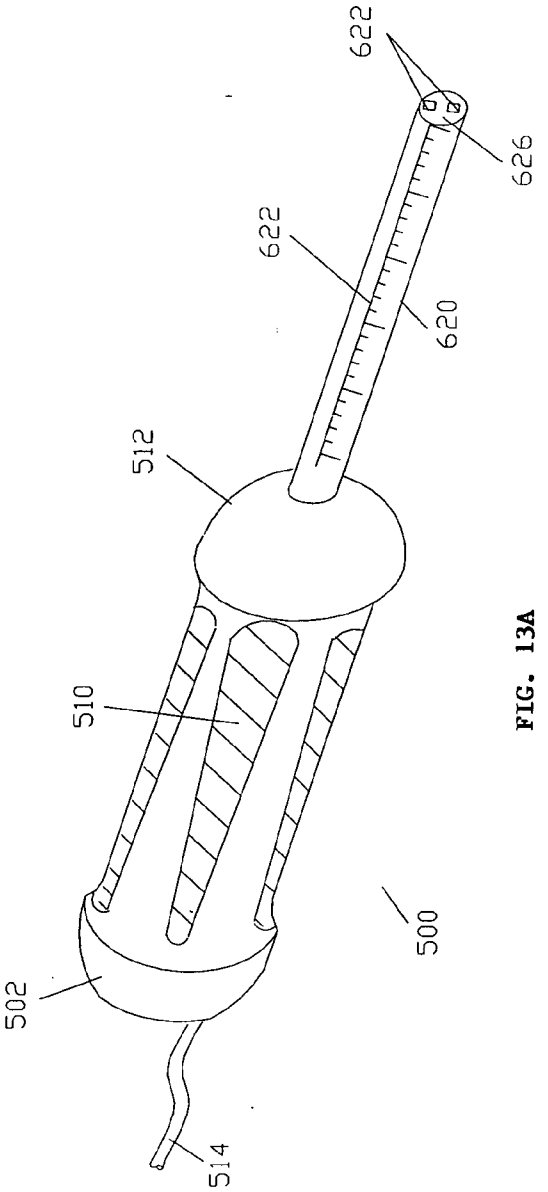


FIG. 13A

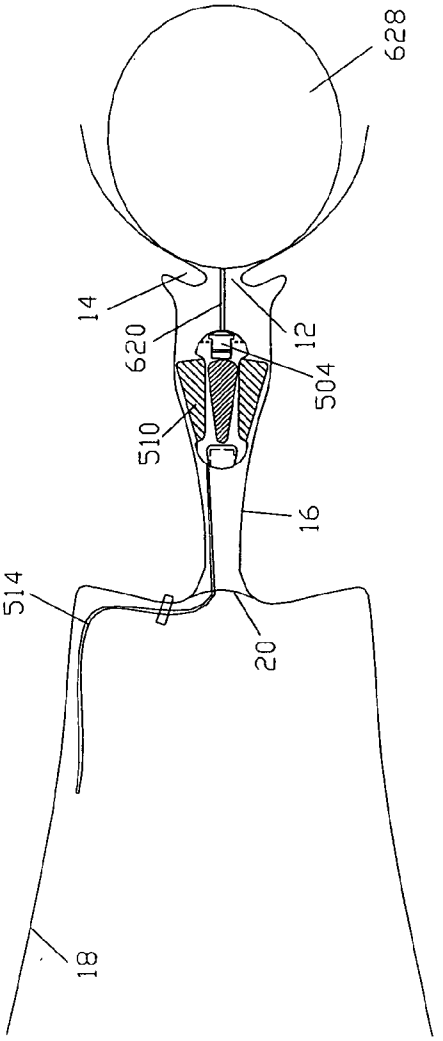


FIG. 13B

# CERVIX MONITORING SYSTEM AND RELATED DEVICES AND METHODS

## CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/498,496, filed Aug. 28, 2003, entitled Method and Devices for Cervix Monitoring; U.S. Provisional Application No. 60/576,479, filed Jun. 2, 2004, entitled Ranging and Imaging Methods for Cervix Monitoring; and U.S. Provisional Application No. 60/587,530, filed Jul. 13, 2004, entitled Probes for Cervix Monitoring, the entire contents of which applications are incorporated herein by reference.

## FIELD OF THE INVENTION

[0002] The present invention relates to a method and system for monitoring progress of labor during childbirth, in particular, changes in the cervix, including changes in the size of the opening of the cervix, during childbirth.

## BACKGROUND OF THE INVENTION

[0003] Monitoring the progress of cervix dilation is desirable during labor because the progress of cervix dilation can be an indicator of various conditions or factors including: (1) arrested or dysfunctional labor, (2) cephalopelvic disproportion, (3) when and whether a Caesarean-section should be performed, (4) when and whether labor inducing/enhancing drugs (e.g. Pitocin) should be used, (5) when should different anesthetic or analgesic agents be administered, and/or (6) when the patient should begin pushing.

[0004] In current clinical practice, cervix dilation (or dilatation, used interchangeably herein) is typically, if not always, monitored manually by a health care provider who inserts a gloved hand into the patient's vagina and then uses his or her fingers to probe and assess the diameter of the cervix opening. This method is known as digital probing and suffers several inherent limitations, including the following. First, the method is approximate as the accuracy of the measurement depends on the experience of the health care provider. Second, the method can cause discomfort to the patient during each session of digital probing which may be performed repeatedly at an interval of 30 minutes or so throughout labor. Third, the health care provider may forget to perform the exam or even avoid it intentionally if the patient is sleeping. Fourth, hand examinations can increase the risk of infection to the patient and the fetus especially if the fetal membranes have been ruptured. In the latter regard, hand examinations may cause complications, including neonatal sepsis to the infant, chorioamnionitis to the fetal membranes, and/or endomyometritis to the uterine muscles.

[0005] As such, hand examinations are often minimized and hence do not provide continuous reliable monitoring of the progress of the labor. In many clinical cases, engagement of the fetus head in the cervix at station +3 (where the presenting part is in the perineum) go unnoticed, especially where the patient is under epidural anesthesia. All of the above factors make desirable the development of an automated technique to continuously, or at least intermittently, monitor cervix dilation and provide an improved, if not more accurate, measurement of the diameter of the cervix opening.

[0006] Current methods for measuring the diameter of the cervix opening during labor are reviewed by Lucidi et al. (Lucidi, R. Scott; Blumenfeld, Lee A.; Chez, Ronald A., "*Cervimetry: A Review of Methods for Measuring Cervical Dilatation During Labor,*"Obstetrical and Gynecological Survey, Volume 55(5), pp 312-320, May 2000) who wrote "although many instruments have been developed to measure cervical dilatation during labor and their use as a research tool has been established, no device has yet been successfully used for clinical obstetrics. The ideal device has not yet been developed; however, because repeated digital cervical examinations are time consuming for the clinician, are poorly reproducible, and are uncomfortable for the patient, continued efforts to develop a cervimeter suitable for clinical use is a worthwhile endeavor."

[0007] As quoted above, there have been many attempts to develop devices for accurate and user-independent monitoring of the diameter of the cervix opening. However, previous techniques failed to gain clinical acceptance due to several limitations, including the complexity of installation, inaccuracy of measurements, tissue trauma caused by the devices or their components, including the manner by which the components are attached to the cervix, blockade of the cervical canal, costly sterilization between uses, and/or patient discomfort. Consequently, the manual method of digital probing continues to be a favored method of monitoring cervix dilation. Therefore, there exists a desire for a system and method which monitor the diameter of the cervix opening during labor in a noninvasive manner and preferably uses a probe that can remain in the vaginal region throughout the course of labor.

## SUMMARY OF THE INVENTION

[0008] The present invention is directed to a minimally invasive system and method for monitoring changes in a cervix opening during labor, including changes in its diameter. The system having a probe and a monitoring unit serve to monitor periodically the cervix opening during labor and obtain measurements of the diameter of the cervix opening. The probe primarily includes a camera for imaging the cervix opening, a lens to provide an optimal field of view for the camera at close range to the cervix opening, a light source to illuminate the cervix and a balloon to expand the vagina around the probe and position the probe to allow unobstructed imaging of the cervix. The balloon is triggered to inflate when images of the cervix opening are taken and can deflate when the camera is not capturing images. A tail or handle portion of the probe facilitates the insertion and removal of the probe from the vagina and protects electrical and pneumatic connections between the probe and the monitoring unit. The tail portion is generally flexible but is adapted to have sufficient rigidity by means of a rod applicator, bead trains or an inflatable body to facilitate the insertion of the probe into the vagina.

[0009] Advantageously, the probe in one embodiment is configured to provide a predetermined distance from which the camera has an appropriate range to image the cervix opening. In one embodiment, a housing of the probe is configured to generally abut the cervix such that the camera fixedly situated in the housing is positioned at the predetermined distance from the cervix.

[0010] In another embodiment, the probe has a disposable portion releasably coupled to a reusable portion. In a more

detailed embodiment, a protective sheath extends from a distal disposable portion of the probe to cover and protect a proximal reusable portion.

[0011] The probe may also have a compartmental balloon or multiple balloons which are symmetrically or asymmetrically disposed around the probe and can inflate simultaneously or separately to selectively orient and position the probe in the vagina. The inflated balloons may also create drainage channels across the probe to allow fluids to flow from the cervix and out of the vagina.

[0012] The present invention also has a probe module that is supported on a distal end of an applicator which releasably holds a probe module until the module has been placed in the vagina at an appropriate distance from the cervix. To that end, the applicator has a range-adjusting structure which may be a coded scale ranging means, a swivel arm means, a string limiter means or an automatic range-adjusting means. In another embodiment, the module itself may carry an optical range means to determine the range between the module and the cervix, which also employs the camera to capture an image of a spot of illumination created by an optical beam of a known spread rate.

[0013] The monitoring unit which controls the probe to acquire images of the cervix and receives and processes image data from the probe includes a processor which uses image segmentation techniques to identify and measure the opening of the cervix and generates data signals. The monitoring unit also includes an image display which displays information based on the data signals for viewing by health care providers and/or the patient, including graphic images of the cervix opening and other text information relating to the cervix opening as an indicator of the progress of labor. In particular, the information display includes measured cervix diameter and dilation rate. One or more monitoring systems may be networked to a remote nursing station to allow the simultaneous monitoring of multiple patients.

[0014] In one embodiment, the processor implements segmentation techniques and/or blob analysis algorithms to analyze the images of the cervix to identify the opening and measure its diameter. Other algorithms may also be implemented to correct for any spatial distortion, particularly barrel distortion. In another embodiment, a portable controller is provided to facilitate the mobility of the patient, by eliminating a cable extending between the probe and the monitoring unit.

## BRIEF DESCRIPTION OF THE DRAWINGS

[0015] These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

[0016] **FIG. 1** is a schematic diagram showing an embodiment of a monitoring system having a self-ranging probe inside the vagina and connected to a monitoring unit.

[0017] **FIG. 2A** is a front view of the self-ranging probe of **FIG. 2B**.

[0018] **FIG. 2B** is a side view of the self-ranging probe of **FIG. 1** with a deflated balloon.

[0019] **FIG. 2C** is a front view of the self-ranging probe of **FIG. 2D**.

[0020] **FIG. 2D** is a side view of the self-ranging probe of **FIG. 1** with an inflated balloon.

[0021] **FIG. 2E** is a side view of a rod applicator of the self-ranging probe of **FIG. 2B**.

[0022] **FIGS. 2F and 2G** are partial side views of an embodiment of a probe handle with bead trains.

[0023] **FIG. 2H** is a partial side view of another embodiment of a probe handle with an inflatable support structure.

[0024] **FIG. 2I** is a cross-sectional view of the flexible tube of **FIG. 2B** taken along lines I to I.

[0025] **FIG. 3A** is a side view of an embodiment of a disposable cap for use with a reusable self-ranging probe.

[0026] **FIG. 3B** is a side view of an embodiment of a reusable core for use with the cap of **FIG. 3A**.

[0027] **FIG. 3C** is a side view of the cap and core of **FIGS. 3A and 3B** releasably coupled to each other.

[0028] **FIG. 4A** is a block diagram of an embodiment of the monitoring system of the present invention.

[0029] **FIG. 4B** shows a network of multiple monitoring systems communicating with a common nursing station.

[0030] **FIG. 5A** shows an embodiment of a graphic user interface and display screen of a monitoring unit.

[0031] **FIG. 5B** shows an alternative embodiment of a graphic user interface and display screen of the monitoring unit.

[0032] **FIGS. 6A and 6B** are photographic images of a normal female cervix with an opening and a normal female cervix with a larger opening.

[0033] **FIGS. 6C and 6D** are the photographic images of **FIGS. 6A and 6B** where the cervix openings have been automatically segmented, measured and outlined in accordance with the present invention.

[0034] **FIG. 7** is a block diagram of an embodiment of a monitoring system of the present invention having a controller unit.

[0035] **FIG. 8A** is a front view of the inflatable-spacer probe of **FIG. 8B**.

[0036] **FIG. 8B** is a side view of an embodiment of an inflatable-spacer probe.

[0037] **FIG. 8C** is a front view of the inflatable-spacer probe of **FIG. 8D**.

[0038] **FIG. 8D** is a side view of an alternative embodiment of an inflatable-spacer probe with drainage members.

[0039] **FIG. 9A** is a front-view of the multi-balloon probe of **FIG. 9B** deflated.

[0040] **FIG. 9B** is a side-view of an embodiment of a deflated multi-balloon probe.

[0041] **FIG. 9C** is an end-view of the multi-balloon probe of **FIG. 9B**.

[0042] **FIG. 9D** is a front-view of the multi-balloon probe of **FIG. 9B** inflated.

[0043] **FIG. 9E** is a side-view of the multi-balloon probe of **FIG. 9B** inflated.

[0044] **FIG. 9F** is an end-view of the multi-balloon probe of **FIG. 9B**.

[0045] **FIGS. 9G and 9H** are front and side views of another embodiment of a multi-balloon probe with an air nozzle.

[0046] **FIG. 10** is an isometric-view of the multi-balloon probe of **FIG. 9B** attached to an applicator.

[0047] **FIG. 11A** is a side-view of an embodiment of a coded scale range-adjusting applicator.

[0048] **FIG. 11B** is a side-view of an embodiment of a swivel arm range-adjusting applicator.

[0049] **FIG. 11C** is a side-view of an embodiment of a string limiter range-adjusting applicator.

[0050] **FIG. 11D** is a side-view of an embodiment of an automatic range-adjusting applicator.

[0051] **FIG. 11E** is a perspective view of the applicator of **FIG. 11C**.

[0052] **FIG. 12A** is a side-view of an embodiment of a probe with range finding capability while measuring range.

[0053] **FIG. 12B** is a side-view of an embodiment of a probe with range finding capability while imaging the cervix.

[0054] **FIG. 13A** is an isometric-view of an embodiment of a probe with a spacer rod with oximetry sensors.

[0055] **FIG. 13B** is a schematic diagram showing the probe of **FIG. 13A** inside the vagina.

## DETAILED DESCRIPTION

[0056] Referring to **FIGS. 1 and 6**, the present invention includes a system S for monitoring dilation of an opening **12** of a cervix **14** of a female patient **15** who is pregnant and in labor to deliver. The system includes a probe **30** that is inserted into a vagina **16** of the patient to gather data relating to the cervix, in particular, the diameter of the opening, and a monitoring unit **13** that is in communication with the probe and receives data from the probe which is processed by a processor to provide and display useful information to health care providers located proximately to the patient and/or remotely therefrom. Advantageously, the probe **30** is adapted to remain in the patient's vagina throughout the duration of labor and assume a suitable position in the vagina so as to gather image data that is sent to the monitoring unit. Accordingly, the patient need not have her cervix digitally probed during labor and may remain relatively undisturbed while changes in the size of the cervix opening are monitored continuously or intermittently as appropriate.

[0057] Disposable Probe

[0058] Referring to **FIGS. 1 and 2**A-2D, a preferred embodiment of the cervix probe **30** includes generally a distal probe head **40** and a proximal probe tail or handle **60** extending proximally from the probe head. The probe head **40** includes a housing **42** encapsulating a lens **44** and a camera **46** that is proximal of the lens and adapted to capture image data of objects within a predetermined field of view **56** of the lens. The housing **42** also contains at least one light source **48** positioned to illuminate the field of view of the lens inside the vagina. The lens **44**, the camera **46** and the light source **48** are fixedly mounted within the housing to the proximal end **53** of the housing. Covering the housing is an inflatable cover or balloon **50** that is sealed to the housing along a circumference **51** at a proximal end portion of the housing **42**. Adhesive and/or a ring clamp may be used to seal the balloon to the housing.

[0059] The probe handle **60** includes a flexible hollow tube **62** having a wall **63** through which a cable **64** extends proximally from the probe **(FIG. 21)** and exits at or near a proximal end of the tube. Extending through the cable are electrical wires **65** extending from the probe **30** to the monitor unit **13** and a fine tube or air conduit **67** whose distal end extends into the housing **42** and terminates at or in the balloon **50** for air or fluid communication therewith.

[0060] The housing **42** may be generally cylindrical in shape along a longitudinal axis **58** with preferably a streamlined distal and proximal ends **41** and **43** to facilitate insertion into and removal from the vagina **16**. Alternatively, the housing may be shaped as the frustum of a cone with a wider distal portion and a narrower proximal portion. The housing has a length in the range of about 2 cm to 5 cm, and more preferably about 4 cm. The housing has a diameter of about 1 cm to 3 cm, and more preferably about 2 cm. The housing **42** may preferably be made of an optically transparent plastic material such as, for example, polycarbonate; however, other materials such as Pyrex may be used. The housing **42** may be hermetic to protect its internal components from contamination and the outside environment. The housing **42** may also be coated or made of a hydrophobic (i.e. water repellent) material to prevent fluids, if any, from adhering to its exposed surfaces. The housing **42** may also have an intermediate depression to accommodate the balloon **50** when deflated.

[0061] The camera **46** is of the miniature type with a size ranging between about 16×16×8 mm and 6×6×3 mm and more preferably 8×8×4 mm. The lens **44** may be a wide angle lens, its field of view (FOV) **56** ranging between about 120 to 190 degrees and more preferably about 170 to 180 degrees to enable imaging of the cervix **14** from a relatively close range. In that regard, the range is generally provided by a predetermined distance or separation **52** between the lens **44** and the distal end **41** of the housing which is also generally the distance between the lens **44** and the cervix **14**, since the probe **30**, as described below in further detail, is adapted to position itself in the vagina with the distal end **41** of the housing generally abutting the cervix or the cervix opening. Accordingly, the camera **46** and the lens **44** are selectively and fixedly situated within the housing **42** at the distance **52** from the distal end **41** of the housing **42**. In particular, the distance **52** is selected to provide enough range to allow the field of view **56** of the lens **44** to capture a fully dilated cervix (at about 10 cm or so) when the distal end **41** of the housing **42** is touching, or is proximate to, the cervix **14** or the opening **12**. The distance **52** may range between about 1 cm to 2.5 cm, and more preferably about 2 cm. The camera **46** may be of any type, including color, grayscale, CCD, CMOS, analog, digital, multispectral, or thermal. Optical filters may also be used to remove certain wavelength bands to enhance the image and/or clarify features of interest such as the opening **12** of the cervix **14**.

[0062] One or more light sources **48** are disposed around the camera to provide the proper illumination necessary for imaging without saturating the camera **46** by, for example, internal reflections off the inner surface of the balloon **50**. The light sources **48** may be light emitting diodes (LEDs) of the miniature surface mount type (SMD), bulbs, or optical fibers. The optical fibers, if used, may have a tip that is polished at an angle to provide side emission. The light sources **48** may emit white or monochromatic light at certain wavelengths, including infrared, to provide better viewing of different tissues/materials, glare reduction and/or improved imaging. The light sources **48** may be aimed at different angles and may be illuminated simultaneously, individually and/or in groups to improve imaging and/or image quality and avoid saturation of the camera **46**.

[0063] The balloon **50** may be made of an optically transparent material such as silicone, latex, polyethylene terephthalate, polyurethane, and/or other materials. The material of the balloon **50** may or may not be elastic. The balloon **50** may be collapsed passively under its own elasticity, and/or actively by suction through the conduit **67** and/or compression from surrounding vaginal tissue. During assembly of the probe **30**, the balloon **50** may be snugly fitted over all or a portion of the housing **42** as shown in **FIG. 2***a* and **FIG. 2***b*, with its end sealed to the housing at the circumference **51**. As such, the deflated balloon **50** may assume the shape of the housing as shown in **FIG. 2***a* and **FIG. 2***b*. A portion or portions of the balloon **50** may be attached directly or tethered to the distal end **41** and the proximal end **43** of the housing **42** such that the housing **42** is suspended within the balloon when it is inflated. The inflated balloon **50** is configured such that it may preferably assume a conical shape (flask-shape) that is coaxial with the housing **42**, with a cone base **49** at the distal end **41** and generally a cone apex **53** at the proximal end **43** of the housing **42** as shown in **FIG. 2***d*. The advantages of this slightly conical inflated balloon shape include: (1) facilitating removal and retrieval of the probe **30** from the vagina **16** even with the balloon inflated, (2) providing maximum vaginal widening close to the cervix **14**, and/or (3) urging of the probe **30** to position itself toward the cervix **14**. Accordingly, upon inflation of the balloon **50**, the distal end **41** of the housing **42** generally borders and axially aligns itself with the cervix **14** and/or the opening **12** to approximately establish the range distance **52** between the lens **44** and the cervix **14** as shown in **FIG. 1**. Advantageously, the conical shape of the probe **30** is adapted to impede sliding proximally in the vagina, toward the vulva **20**, while facilitating sliding toward the cervix **14**. Moreover, to limit sliding of the probe proximally toward the cervix **14** (which may allow the probe to become misaligned with the cervix), the cable **64** extending from the vagina may be fixed to the thigh **18** of the patient **15** using adhesive tape to tether the probe to the thigh. Furthermore, as mentioned, the conical balloon shape with its apex **53** directed toward the vulva **20** also facilitates the removal of the probe **30** from the vagina **16** even with the balloon **50** inflated. In addition, the conical shape of the inflated balloon **50** better conforms to the shape of the inner portion of the vagina **20** during labor.

[0064] Alternatively, the balloon **50** may assume any other generally axially symmetrical shape when inflated provided it avoids distorting or obstructing the field of view **56** of the lens **44** and the camera **46**. Other shapes of the balloon **50** include spherical, elliptical, egg-shaped, cylindrical, ribbed-cylinder, star, and cuboidal. Yet alternatively, the balloon **50** may be multi-compartmental and/or composed of two or more inflatable chambers **510** that may be inflated either simultaneously, individually, or in groups using separate tubes to control the spatial orientation of the probe **30** within the vagina **16** (see **FIGS. 9A-9F**). Inflation and deflation of the balloon via the conduit may be automated by the processor as part of image processing algorithms. For example, the processor may continue to inflate the balloon until the image processing algorithms can identify the opening of the cervix in images acquired by the camera **46**.

[0065] The balloon **50** is attached to the housing **42** such that it expands symmetrically about the axis **58** to provide the lens **44** and the camera **46** with a centered view of the opening **12** of the cervix **14**. Alternatively, the balloon **50** may be attached to the housing **42** such that it expands asymmetrically about the axis **58** of the housing **42** when inflated to obtain an off-centered view of the opening **12** of the cervix **14**. The latter configuration may help minimize any optical effects or distortion of the distal end of the housing. In any case, any optical effects or distortion in the image data caused by the distal end **41** may be compensated for and corrected by the image processing algorithms.

[0066] The probe handle **60** includes a generally flexible tube **62** emerging proximally from the proximal end **43** of the housing **42**. The tube **62** may be made of silicone, latex, Tygon or any other flexible tubing material. The outer diameter of the tube **62** is no greater and preferably smaller than the diameter of the housing **42** as shown in **FIGS. 2B and 2D**. The tube **62** is preferably long enough to allow it to exit the vagina **16** when the distal end **41** of the housing **42** is in contact with the cervix **14**. A suitable length ranges about 10 cm to 18 cm and more preferably about 12 cm to 14 cm. A wall of the tube **62** may be configured with an aperture to enable the cable to exit at or near the proximal end of the tube and extend to the monitoring unit **13**. It is understood by one of ordinary skill in the art that the electrical connection between the probe **30** and the monitoring unit **13** by which image data and/or control signals are sent and received need not be accomplished by wires but that it can be wireless as well, or a combination of the two.

[0067] In accordance with the present invention, the handle **60** provides several advantages, including: (1) preventing a total collapse of the vagina **16** proximal to the probe head **40** so as to minimize vaginal irritation upon sudden withdrawal of the probe **30** from the vagina, (2) allowing convenient removal, adjustment, and reinsertion of the probe **30**, (3) providing stabilization and centering of the probe **30** with minimal discomfort to the patient **10**, and/or (4) protecting the cable **64** of the probe. In another embodiment of the handle **60**, the wall of the tube **62** may be configured along its length with drainage holes (not shown) to facilitate seepage into the tube of any fluids present in the vagina **16** and drainage of the fluids out of the proximal end of the tube.

[0068] The probe handle **60** may include an applicator or shaft **70** to reinforce the flexible tube when the probe **30** is inserted into the vagina **16**. The applicator **70** is generally a rod **72** that is inserted into a lumen **66** of the tube and advanced distally until its distal tip **74** engages a docking hole **68** configured in the proximal end **43** of the housing **42**. After the probe **30** is inserted into the vagina **16**, the

applicator **70** is drawn from the lumen **66** to restore the flexibility of the tail **60**. A proximal end of the applicator has a gripping knob **76** to facilitate handling of the applicator **70** and/or the probe **30** by a health care provider.

[**0069**] In an alternative embodiment as shown in **FIGS. 2F and 2G**, the lumen **66** may permanently house a train of beads **61** to provide the appropriate structural support to the tail **60** when being inserted into the vaginal while maintaining the flexibility of the tail to minimize post application discomfort. The beads may be preferably semi-cylindrical as shown in **FIG. 2F** and/or semi-spherical and preferably hollow to reduce their weight. The beads may have articulating ends such that a protrusion from one bead would articulate in a socket in adjacent bead(s) and so forth as shown in **FIG. 2G**. Moreover, the beads may be threaded with a tension string that can be used to temporarily compress the beads and convert them to a stiff rod only during the insertion of the probe **30**. Yet alternatively, the lumen **66** may include an inflatable body **59** as shown in **FIG. 2H** that may be temporarily inflated by air or liquid to reinforce the tail **60** and facilitate the insertion of the probe **30** into the vagina **16**. The inflatable body **59** may be inflated or deflated via a dedicated air or fluid conduit in the cable **64**.

[**0070**] The cervix probe **30**, even when inflated, can be removed relatively quickly from the vagina **16** by manually holding grip treads **69** on the proximal end of the tube **62**, which is preferably extending outside of the vagina, and pulling the probe **30** proximally The cable **64** may have an inter-connector member (not shown) that is adapted to connect with an extension cable (not shown) connected to the monitoring unit. This configuration may allow a shorter cable to be used with the probe.

[**0071**] Reusable Probe

[**0072**] **FIGS. 3A, 3B** and **3**C show an alternative embodiment of the probe which provides disposable (typically less costly) components and reusable (typically more costly) components. A probe **100** as shown in **FIG. 3A** has many structural similarities to the probe **30** of **FIG. 2**; however, the probe **100** is configured with a cap **110** that is disposable and a core **130** that is reusable, where the cap and the core are releasably coupled to each other. In one embodiment, the housing is divided into a cap housing **112 (FIG. 3A)** and a core housing **132 (FIG. 3B)**. The cap housing **112** defines an interior **114** accessed via an opening **115** that is adapted to receive a distal portion of the core **132**. The cap **110** also includes a balloon **116** covering the cap housing **112**, and a condom-style protective sheath whose distal end is attached to the cap housing at the circumference **151** and whose proximal portion **122** is rolled up at or near the opening **115** of the cap housing **112** which has an interior threaded portion **120**. The cap housing is also configured with an aperture **118** through its wall to provide a passage way for air to inflate the balloon **116**, which is similarly sealed at the circumference **51** (see **FIG. 1**), as well as exit from the balloon when deflating.

[**0073**] The core **130** shown in **FIG. 3B** is composed of the core housing or base **132** on to which are fixedly mounted a lens **134**, a camera **136** proximal of the lens and a light source **138** generally adjacent to the lens to illuminate a field of view of the lens. The core housing **132** is configured on its exterior with a threaded portion **140** suitable for releasably coupling the core housing **132** to the cap housing **112**. The core **130** also includes an air outlet **142** adapted for communication with the air passage way **118** at one end and with the conduit **67 (FIG. 2B)** at the other end, and a gasket **144** to seal the coupling between the core **130** and the cap **110**. All or part of the cap housing **112** and the core housing **132** may be optically transparent to allow a relatively unobstructed field of view for imaging the cervix **14**.

[**0074**] Prior to inserting the probe **100** into the vagina, the probe is assembled by placing the cap **110** over the core **130** and connecting the cap and the core to each other, for example, by the threaded portions. As understood by one of ordinary skill in the art, the use of screw thread is not restrictive and other locking mechanisms to releasably couple the core and the cap, for example, a snap fit configuration, may be used. The gasket **144** seals the interior **114** between the cap **110** and the core **130**. The distal end of the air conduit **67** is in communication with the air outlet **142** of the core housing **132** which is in communication with the distal portion of the balloon via the aperture **118**. There may be additional apertures in the housing **112** that permit air to pass between the interior **114** and the balloon **116**. As described before, air is pumped through the air conduit **67** to reach and inflate the balloon **116** and air is expelled from the balloon through the air conduit **67** when deflating the balloon. The above pneumatic means of connecting and communicating air to and from the balloon is not restrictive and other configurations may be used. For example, in an alternative embodiment, the pneumatic connection may be accomplished by a male tube in the core **130** that plugs into a female receptor hole in the cap **110** to establish pneumatic continuation upon placement of the cap **110** over the core **130**. In any case, after attaching the cap **110** to the core **130**, the proximal portion of the protective sheath may be unrolled and deployed over the core **130** and the tail **146** as shown in **FIG. 3***c* to cover and protect them from contamination by fluids or debris in the vagina **16**. The proximal portion **122** of the protective sheath is of a length to adequately cover the tail **146** and cable **164** to outside of the vagina **16** and preferably by a sufficient length beyond the vulva **20**. The cable **164** may be taped to the thigh **18** of the patient **15** to prevent any unintended dislodging of the probe **100** from the vagina.

[**0075**] Following use of the probe **100**, the core **130** is decoupled from the cap **110** and the cap **110** is discarded or otherwise disposed of. The core **130** on the other hand may be sterilized using common medical detergents and/or cleaning agents for reuse with another cap. Other features of the probe are similar to the disposable probe **30** of **FIG. 2** and generally the same specifications and functions apply.

[**0076**] The Monitoring Unit

[**0077**] Referring to **FIG. 4***a*, a block diagram of an embodiment of a system of the monitoring unit **13** is shown in use with the probe **30**. The unit **13** has a power supply **312** supplying power to the system S, a pump **304** for supplying air to and drawing air from the balloon **50** of the probe **30**, a flowmeter **303** to monitor the flow into and out of the balloon, a pressure sensor **306** to monitor the pressure of the balloon, a video digitizer **310** that digitizes the image data from the probe **30**, a processor **300** that controls the operation of the probe **30** and the system S, and an image display **314**. The processor receives and processes the image data provided by the probe, including an implementation of the

image processing algorithms that process the image data provided by the probe, and sends data signals to the image display, which displays information relating to the changes in the cervix opening as an indicator of the progression of labor.

[0078] A cable connector **17** facilitates releasable connection of the probe cable **64** to the monitoring unit M. The cable connector **17** includes both electrical connectors and tube connectors. The pump **304** may be a low-noise bidirectional air pump or a bidirectional liquid pump to pump saline or any other suitable fluid to inflate the balloon **50**. The pressure sensor **306** may be used to measure pressure in the balloon **50** and control the pump **304**. It is understood by one of ordinary skill in the art that the pressure sensor **306** may be situated in the monitoring unit **13** as shown in **FIG. 4***a*, or alternatively in the probe **30** and connected to the monitoring unit **13** using wires in the cable **64**. If the pressure sensor **306** is situated in the monitoring unit **13**, a special control protocol may be required to measure a true air pressure in the balloon.

[0079] During pumping, the pressure measured at the pump **304** may not be equal to the pressure in the balloon **50** because of the airflow resistance of the air conduit **67** connecting the pump **304** to the balloon **50**. As such, the pressure in the balloon may be measured using an alternating pump activation, deactivation, and pressure measurement protocol as follows: (1) The pump is activated for a period T1 and then deactivated, (2) A period T2 is provided such that pressure between the balloon **50** and the output of the pump **304** to which the pressure sensor **306** is connected is permitted to equalize, (3) The pressure is measured at the output of the pump **304**, (4) The pump is activated again and so forth until the desired pressure is reached. The period T1 may be dynamically varied depending on an expected incremental increase in pressure. For example, T1 may be shortened as the pressure increases.

[0080] The flow meter sensor **303** measures the air volume pumped into or out of the balloon **50**. This air volume information may be used along with or separate from the pressure information measured by the pressure sensor to control the pump until a desired volume is moved into or out of the balloon **50**. The air volume to be pumped into the balloon may be adjusted depending on the latest measured diameter of the opening **12** of the cervix **14**. The air volume to be pumped out of the balloon may be equal to the last air volume pumped into the balloon. The processor **300** may use an analog to digital converter **308** to acquire the measurement of the flowmeter **303** and the pressure sensor **306**.

[0081] The video digitizer **310** may be used to digitize the video signal from the camera **46** of the probe **30** and convert it to a digital image for processing by the processor **300**. Alternatively, a camera controller (not shown) may replace the video digitizer **310** where the camera is of the digital type. The power supply **312** may be used to power the components of the cervix probe **30** and the monitoring unit **13**.

[0082] In one control sequence, a switch (not shown) in the cable connector **17** may trigger the processor **300** when the probe **30** is plugged into the monitoring unit **13**. The processor **300** automatically powers up the camera **46**, the light source **48**, the video digitizer **310** and the display **314** to provide live video guidance to aid the user in positioning the probe **30** in the vagina **16** (e.g. next to the cervix). Alternatively, the probe **30** may be blindly inserted into the vagina **16** until the user determines that it cannot be advanced any further. At this position, the distal end **41** of the housing **42** should be touching the cervix **14**. After the probe **30** has been appropriately positioned in the vagina **16**, the processor **300** may begin to acquire measurements using the following cycle:

[0083] 1. The processor **300** may activate the pump **304** to inflate the balloon **50** up to a volume and/or pressure level that is predetermined to sufficiently expand the vagina for proper imaging of the cervix **14**.

[0084] 2. The processor **300** may activate the camera **46**, the light source **48**, and the video digitizer **310** to capture an image of the cervix **14** and its opening **12**.

[0085] 3. The processor **300** may reversibly activate the pump **304** to deflate the balloon **50** to the pre-inflation volume and/or pressure.

[0086] 4. The captured image may be initially preprocessed to correct for any optical distortions (e.g. barrel distortion) that may be caused by the wide-angle lens **44**, the housing **42** and/or the balloon **50**.

[0087] 5. The distortion-corrected image is processed using image-processing algorithms as described below to identify the cervix opening **12**, measure its diameter, and calculate the dilation rate from any sequential measurements.

[0088] 6. The captured image is displayed on the display **314** along with, for example, its corresponding diameter of the cervix opening **12** and the dilation rate. Examples of preferable display modes are shown in **FIG. 5**.

[0089] The above data acquisition cycle is not mandatory and other operation sequences may be used if desired, as understood by one of ordinary skill in the art. The data acquisition cycle may be repeated every 30-minutes or at any different rate that is selected by the user.

[0090] The display **314** may be of the touch-screen type and may be divided into a control section **315** and a data display section **317**. The control section allows the user to select operating parameters. The user may use a graphical switch **320** to select between two data display modes, for example: (1) a Combo mode as shown in **FIG. 5***a* or (2) an Images mode as shown in **FIG. 5***b*. Also, the operator may use the graphical switch **322** to select a view of normal images or a view of segmented images with the opening **12** of the cervix **14** graphically outlined. Slide show control buttons **324** allow the user to activate a series or slide show sequencing the images of the cervix **14** one after the other in the display section. The operator may also: (a) use a window **326** to select a cervix probing rate in units of samples per hour, (b) use a window **328** to select an alarm level to warn when the opening of the cervix reaches a certain diameter, (c) use a window **330** to select an alarm level to warn when the dilation rate is abnormally slow relative to the stage of labor and/or the diameter of the cervix opening **10**, (d) use a graphical button **332** to manually control the inflation/deflation of the balloon **50** and/or (e) use a graphical button and slider **334** to perform manual segmentation of the initial cervix image. The parameters setting of this initial manual segmentation may be applied to automatic segmentation of subsequent images.

[0091] The display section of the Combo Screen shown in **FIG. 5***a* displays generally: (1) a cervix image **340** in the window **342**, (2) a cervix dilation graph **344** plotting the diameter of the cervix opening **12** versus time, and/or (3) a set of numerical values, including the automatically measured diameter of the cervix opening **346**, the previous diameter measurement **348**, the dilation rate **350**, user-measured distance **352** obtained by positioning two cursors **354** on the cervix image **340**. The Time "0" on the time axis **356** of the graph represents the latest (or current) measurement while negative values represent past time. For example, the "−4" indicates four hours earlier. The user may use a pointing device to position two cursors **354** on the cervix image **340** to measure any desired distance and display the resulting value window **352**.

[0092] Each point in the cervix dilation graph **344** may be clicked on or otherwise selected to display its corresponding image of the cervix opening in the window **342**. The circle or marker **358** highlights the data point associated with the cervix image **340** displayed in the window **342**. The window **342** displaying the cervix image **340** may have a horizontal ruler **360** and a vertical ruler **362** to allow the eyeballing of physical dimensions (i.e. cm). A grid may be superimposed on the window **342** if desired. Text comments **364** are possible prompts or suggestions of actions that may be taken when a specific diameter is reached.

[0093] The Images Screen shown in **FIG. 5***b* generally displays a series of images **370** showing the cervix **14** as it dilates throughout labor. Each image is stamped with: (1) a time of its acquisition **372**, and (2) an automatically measured diameter of the cervix opening **374**. The sliding indicator **376** gives a graphical impression of the temporal location of the image highlighted by the frame **378**.

[0094] The monitoring unit **13** may include a transmitter **317** to transmit the acquired images of the cervix and other corresponding information including the cervix diameter and dilation rate to a remote station, such as a nursing station **93** and/or a television **95**. The transmitted signals may be transmitted on different frequencies or digitally coded to prevent the interference of signals upon reception. The transmitted signals may be also encrypted for security purposes. The monitoring unit **13** may also include a receiver (not shown) for bidirectional communications to receive operation instructions from the nursing station **93**. Clearly, it is understood by one of ordinary skill in the art that multiple systems $S_1$-$S_N$, with multiple units $\mathbf{13}_1$-$\mathbf{13}_n$ and their respective probes $\mathbf{30}_1$-$\mathbf{30}_n$, can be configured to communicate with each other and/or one or more nursing stations as a monitoring network for monitoring different patients as shown in **FIG. 4***b*.

[0095] Image Processing

[0096] The captured image of the cervix may be preprocessed to correct for any spatial distortion caused by the wide-angle lens **44** of the camera. The wide-angle lens **44** (i.e. fisheye) (**FIG. 1**) may be used to enable the imaging of a fully dilated cervix **14** from a relatively close distance of approx. 2 cm. Wide-angle lenses can introduce an image distortion known as the barrel distortion, which is caused by the uneven magnification between the edges and the center of the lens. Barrel distortion is a type of radial distortion in which horizontal and vertical lines appear to be bent outwards toward the edges of the image. Algorithms to correct barrel distortion in images are readily available in the literature, e.g., Mundhenk, T. N., et al., "Techniques for fisheye lens calibration using a minimal number of measurements," Proceedings of the SPIE, SPIE-Int. Soc. Opt. Eng., 4197, pp. 181-90, 2000, and e.g. James P. Helferty, et al., "Videoendoscopic Distortion Correction and Its Application to Virtual Guidance of Endoscopy," IEEE Transactions on Medical Imaging, Vol. 20, No. 7, pp 605-617, 2001. These algorithms may be applied to the images captured by the video digitizer **310** (**FIG. 4***a*) to minimize or remove barrel distortion. In addition, algorithms for the correction of perspective distortion (e.g. Waltz, F. M., "Implementation of real-time perspective correction," Proceedings of the SPIE—SPIE-Int. Soc. Opt. Eng. 849, pp. 179-83, 1988) may be also applied to correct for distortions caused by the non-perpendicular imaging of the cervix (i.e. when the probe is at a tilted viewing angle of the cervix). The distortion-corrected images may be color balanced and filtered using, for example, a median filter to improve image quality.

[0097] Moreover, images of the cervix acquired by the probe may be visually contaminated by the presence of biological fluids, mucus, etc., on the cervix during its imaging. This may require special preprocessing to enhance the image quality before applying the segmentation algorithms for the identification and measurement of the cervix opening. One method to improve image quality may be to average images captured under different illumination settings (e.g. angle, intensity or color). Another method may be to use images captured from two or more separate balloon inflations. This may be achieved by inflating the balloon, capturing a first image, slightly deflating the balloon, immediately re-inflating the balloon to capture a second image. The first and second images may be used individually to measure the diameter of the cervix; e.g., the two measured diameters are averaged to determine the actual diameter and/or an effective diameter of the cervix opening. Alternatively, the first and second images may be averaged and the resulting image used to measure the diameter of the cervix opening.

[0098] The processor **300** may use image segmentation techniques and/or blob analysis algorithms to analyze the images of the cervix **14** to identify its opening **12** and measure its diameter. Blob analysis is a branch of image analysis that allows the identification of connected regions of pixels (known as blobs) within an image. Once these regions are identified, one can calculate selected features of those regions, automatically discard regions that are not of interest, and classify the remaining regions according to the values of the features. A blob region may be identified by segmenting the image such that the pixels of an object have the same logical state. Regions of touching pixels in this state are identified as a blob. Pixels not part of a blob may be considered as image background.

[0099] Segmentation is a well-known image processing method that is used to isolate a desired image features or object from background of the image. It is commonly used in blob analysis, machine vision and medical imaging. In this case, object segmentation is applied to isolate the opening of the cervix from the rest of the image. The segmentation techniques applied may include intensity thresholding, color thresholding, active contours, region growing, and/or level set analysis. The above methods are described in known literature, e.g., Pratt, William K., Digital

Image Processing, John Wiley & Sons, New York, 2001, and e.g., Jahne, Bernd, Image Processing for Scientific Applications, CRC Press, New York, 1997, and may provide a reliable and accurate means to isolate and measure the opening **12** of the cervix **14**. The area of the segmented objects within the image may be compared to preset values of minimum and maximum areas of the cervix opening to automatically discard objects with unrealistic dimensions or areas. The processor **300** may counts the number of pixels within the segmented opening of the cervix and converts the number of pixels to an area in real dimensions ($cm^2$). The actual physical dimensions of each pixel are pre-known since the lens **44** of the camera **46** is separated by a known distance **52** from the cervix **14** using, for example, the probe embodiment described in **FIG. 2**. Assuming the cervix opening during labor is circular, the average diameter "D" of the cervix opening may be approximately calculated using the following formula:

$$D = \sqrt{\frac{4 \text{ Segmented Area } [\text{cm}^2]}{\pi}} \quad [\text{cm}^2]$$

**[0100]** The measured diameter value "D" may be compared to the previously measured diameter, if any, to calculate the dilation rate. The processor **300** then displays the preprocessed image of the cervix, the measured diameter, and dilation rate on the display **314**.

**[0101]** Although the above image-processing techniques are described with one probe embodiment as an example, it should be appreciated that these image-processing techniques may be used with any of the alternative probe embodiments described herein.

**[0102]** **FIG. 6***a* is a photographic image of an actual cervix with a generally centered cervix opening of a certain diameter. **FIG. 6***c* is the image of **FIG. 6***a* after it has been segmented and analyzed to identify the cervix opening and measure its area. The computer outlined area in **FIG. 6***c* measures approximately 221 pixels.

**[0103]** **FIG. 6***b* is photographic image of an actual cervix with a generally cervix opening of a greater diameter. **FIG. 6***d* is the image of **FIG. 6***b* after it has been segmented and analyzed to identify the cervix opening and measure its area. The computer outlined area in **FIG. 6***d* measures approximately 522 pixels.

**[0104]** Since the lens has a known magnification, the above pixel areas may be converted into physical area and used in the above equation to calculate the approximate average diameter of the cervix opening.

**[0105]** Portable Controller

**[0106]** As another alternative embodiment, a portable wireless controller **400** may be used to facilitate the mobility of the patient **15** by eliminating the cable **64** connecting the probe **30** to the monitoring unit **13**. The main components of a wireless controller **400** are shown in the block diagram of **FIG. 7**. The controller **400** includes a processor **406**, a bidirectional air pump **408**, a pressure sensor **410**, a camera and light-source driver **412**, and a transmitter **414** as shown in **FIG. 7**. The controller **400** is compact and may be attached to the thigh **18** of the patient **15** using a belt or any other means of attachment. The probe **30** may be connected to the controller **400** using a connector **401**. The controller **400** may communicate wirelessly with the monitoring unit **13**, a remote nursing station **93** and/or an image monitor such as a television **95**.

**[0107]** In a typical cervix measurement sequence, the processor **406** triggers the pump **408** to inflate the balloon **50** up to a certain predetermined pressure that is monitored by the pressure sensor **410**. The inflation of the balloon **50** widens the vagina **16** and allows the lens **44** to have an unobstructed view of the cervix **14**. The processor **406** then powers the light sources **48** and the camera **46** to image the cervix **14** and/or the opening. The processor **406** transmits the images of the cervix **14** using the transmitter **414** to the corresponding monitoring unit **13**, the nursing station **93**, and/or the television **95** which may be located in the patient's room. Alternatively, the controller **400** may process the images of the cervix **14** to measure the diameter and calculate the dilation rate, for example, using an ASICS. The diameter and dilation rate may be displayed on an onboard display **416** and/or transmitted along with identifying information to the corresponding monitoring unit **13**, the nursing station **93**, and/or the television **95** in the patient's room.

**[0108]** The transmitter **414** may be of the analog or the digital type. The transmitted signals **420**, **422** and **423** may be either transmitted on different frequencies or digitally coded to prevent the interference of signals upon reception. The transmitted signals **420**, **422** and **423** may be also encrypted for security purposes. The controller **400** may also include a receiver (not shown) for bidirectional communications to receive operation instructions from the corresponding monitoring unit **13** and/or the nursing station **93**.

**[0109]** Other Embodiments of the Cervix Probe

**[0110]** Capsule Balloon with Inflatable Frontal Spacer

**[0111]** Another embodiment of a cervix probe **200** is shown in **FIG. 8** where a balloon **210** expands into a capsule or bubble around the probe housing **202** to allow proper imaging of the cervix **14**. The probe **200** is composed of a housing **202**, a lens **204**, a camera **206**, and light sources **208**, and the balloon **210**. The lens **204** and the camera **206** may be positioned at the distal end of the housing **202** and has a field of view **256**. The balloon **210** is positioned around the housing **202** such that it expands both radially and distally with respect to an axis **214** of the housing **202**. The radial expansion opens the vagina to create an unobstructed field of view for the lens **204** and the camera **206** to image the cervix **14**. The distal expansion creates a predetermined separation distance or range **216** between the lens **204** and the cervix **14** to: (1) provide enough range to allow the field of view **256** to capture a fully dilated cervix (at diameter about 10 cm or so) when the distal end **220** of the balloon **210** is touching, or is proximate to, the cervix **14** or the opening **12**, and (2) maintain the dimensional calibration of the image by having a known distance between the lens **204** and the cervix **14**.

**[0112]** The balloon **210** may be made of an optically transparent material such as silicone, latex, polyethylene terephthalate, polyurethane, or other materials. The material of the balloon **210** may or may not be elastic. The balloon **210** may be collapsed passively under its own elasticity or actively by suction. The balloon **210** may include support

lines **218** (or tether ribbons) to hold the housing **212** in place and to limit distal expansion to maintain the separation distance **216** when the balloon is inflated.

[**0113**] The balloon **210** may be composed of multi-chambers or compartments that can be separately inflated for the independent control of the radial and distal expansions of the probe **200**. Alternatively, two or more separate balloons may be used for the independent control of the radial and distal expansion of the probe **200**. For example, first balloon may be used for radial expansion to widen the vagina while a second balloon may be used for distal expansion to create a known distance between the lens and the cervix.

[**0114**] With this embodiment, the cervix probe **200** may be placed in the vagina **16** such that a distal end **220** of the inflated balloon borders or touches the cervix **14** or its opening **12**. The probe cable **224** may include wires and fine tubes to connect the probe **200** to the monitoring unit **13**. The proximal end of the extension cable **224** has tube/wire connector **17**, which plugs into the monitoring system **13**. The proximal portion of the probe **200** may include a docking hole **217** where the distal end **531** of the applicator **530** (described below) may engage to hold the probe **200** prior to its application into the vagina **16**. Alternatively, the probe **200** may include a handle similar to the handle **60** and use an applicator similar to the applicator **70** described above for the embodiment of probe **30**.

[**0115**] Alternatively, radial surface of the balloon may have longitudinal draining tubes **222** arranged in radial symmetry about the axis **214** as shown in **FIG. 8***c* and **FIG. 8***d*. The longitudinal draining tubes **222** allow passage of any fluids proximally along the cervix probe **200** when the balloon is inflated so as not to occlude the vagina **16** and dam the fluids leaking from the cervix **14**. The longitudinal draining tubes **222** may preferably have a rectangular cross-section, however, they may assume any other cross-sectional shape including circular, semicircular or square.

[**0116**] Multi-Balloon Conical Probe

[**0117**] Yet another embodiment of a cervix probe or probe module **500** is shown in **FIGS. 9A-9F** where the probe **500** includes a housing **502**, a lens **504**, a camera **506**, and light sources **508**. Multiple elongated inflatable bodies or balloons **510** are disposed radially about probe housing **502**. The probe may have at least three inflatable bodies and, more preferably, at least four inflatable bodies disposed symmetrically about the probe housing. Front, side and back views of the preferred embodiment of the multi-balloon cervix probe **500** are shown in schematic diagrams of **FIGS. 9A-9F**.

[**0118**] The lens **504**, the camera **506**, and the light sources **508** are placed within a protective housing **502** and sealed from the outside environment. The protective housing **502** may be made of plastic and coated with silicone. The plastic and/or the silicone may be optically transparent. An optically transparent front shield **512** protects the lens **504** of the camera **506** and its surrounding light sources **508**. The light sources **508** may be placed behind the shield **512** and optically coupled to the inner surface of the shield **512** to minimize back reflection into the camera **506**. Alternatively, the light sources **508** may be placed on the outer surface of the shield **512**, the housing **502**, or the balloons **510** to provide optimal illumination of the cervix **14**. The shield **512** is made of (or coated with) a hydrophobic (i.e. water repellent) transparent material to prevent fluids from adhering to its surface and obstructing the view of the camera. In addition, the front shield **512** may include an air nozzle **515** **(FIGS. 9G and 9H)** to emit short bursts of air (or saline) onto a front surface of the shield **512** to remove debris or fluids present thereon.

[**0119**] The streamlined housing **502** may be cylindrical and has smooth parabolic-shaped ends as shown in **FIG. 9** to facilitate its insertion into and removal from the vagina **16**. The outer surface of the housing **502** may have a shallow depression **503** to accommodate the balloons **510** when deflated. Each balloon **510** may preferably assume a conical shape when inflated. The balloons **510** may be arranged in a star configuration around the housing **502** such that the probe **500** may have a generally conical shape when the balloons **510** are inflated. An apex of the conical shape may be at a distal end of the probe **500** where the cable **514** exits. The generally conical shape of the probe **500** impedes movement or sliding distally, if any, out of the vagina **16** while enhancing movement or sliding proximally toward the cervix **14**. Any sliding motion of the probe **500** toward the cervix **14** may be limited by fixing the cable **514** to the thigh **18** of the patient **15** using adhesive tape. The conical shape with its apex directed toward the vulva **20** also facilitates the removal of the probe **500** from the vagina **16** even with the balloons inflated. In addition, the conical shape better conforms to the shape of the vagina during labor.

[**0120**] The balloon **510** may be made of silicone, vinyl, latex, polyethylene terephthalate, polyurethane, or any biologically safe balloon material. The material of the balloon **510** may or may not be elastic. The balloon **510** may be collapsed passively under its own elasticity or actively by suction of the pump. The balloons **510** may be inflated either simultaneously or individually (e.g. using separate air tubes) to adjust the spatial orientation of the probe **500** within the vagina **16**. The longitudinal space gaps **511** between the elongated balloons may serve as channels through which fluids can pass along the probe **500** and drain out of the body. A proximal portion of the body **502** of the probe **500** may include longitudinal channels (or grooves) **513** to facilitate the drainage of the fluids passing through the longitudinal space gaps **511**.

[**0121**] After the cervix probe **500** is positioned at a selected location within the vagina **16**, the balloons **510** are inflated to: (a) locally widen the vagina **16** and allow a better view of the cervix **14**, and (b) releasably anchor the probe **500** at the selected location. A bedside monitor **13** may sense and adjust the pressure in the balloons **510** to maintain it at a minimum level that is needed to anchor the probe **500** and widen the vagina **16** for imaging the cervix **14**.

[**0122**] A flexible cable **514** of the cervix probe may be attached to the patient's thigh **18** using an adhesive tape. The flexible cable **514** includes electrical wires and tubes to connect the probe **500** to the monitoring unit **13**. The cervix probe **500** can be removed relatively quickly from the vagina **16**, even while inflated, by drawing the flexible cable **514** proximally. In that regard, the cable should have enough strength and durability to withstand the tension forces during pulling. For this purpose the flexible cable **514** may include a non-expansible fine plastic line (e.g. fishing line) bundled with the electrical wires and tubes to enhance its tensile

strength. The flexible cable **514** may have an inter-connector (not shown) and an extension cable (not shown). This arrangement may allow the use of a shorter cable **514**. The inter-connector may have an air valve to minimize or prevent air leakage from the balloons when the cable **514** is disconnected from the extension cable. The proximal end of the extension cable **514** has tube/wire connector **92**, which plugs into the bedside monitor **13**. The proximal portion of the probe **500** may include a docking hole **516** where the distal end of the applicator **530** may engage to hold the probe **500** prior to its application into the vagina **16**.

[**0123**] Range-Adjusting Applicators

[**0124**] Prior to its application in the patient's vagina, the probe **500** sits on or in the distal end **531** of a rod-shaped applicator **530** as shown in **FIG. 10** to facilitate the insertion of the probe **500** into the vagina **16**. A proximal end **533** of the applicator shaft **532** has a probe release button **536** to release and deploy the probe **500** from the applicator **530**. A distal end **531** of the applicator **530** includes a mechanism to hold the probe **500** until released by the user. The holding mechanism (not shown) may be retractable locking lips that engage into corresponding notches in the probe's docking hole **516**, a Velcro attachment pair, a magnetic pair, or by simple friction. Pressing the release button **536** against the wings **538** translates distally a release rod (not shown) within the shaft **532** of the applicator **530** so that the distal tip of the release rod (not shown) pushes the probe **500** forward to disengage from the distal end **531** of the applicator **530** and lodge within the vagina **16**. The applicator **530** may also have range-adjusting features to aid the user in placing the probe at a predetermined distance from the cervix **14** as described below. Advantageously, the range-adjusting features maintain the calibration of the camera sensor to physical dimensions in the vagina.

[**0125**] In one embodiment, a range adjuster includes a linear scale **540** printed along a segment of the shaft **532** as shown in **FIG. 11***a*. The linear scale **540** may be numbered, graduated and/or color-coded to assist the operator in positioning the probe **500** at a predetermined distance from the cervix **14**. In a typical probe placement procedure, the probe is inserted into the vagina **16** until the distal ends abuts the cervix **14**. This may be done under live video guidance from the camera **506** and/or by gently introducing the probe **500** until further distal advancement is blocked by the cervix. The operator then looks at the scale **540** and takes note of the number and color background color closest to the vulva **20**. The operator then withdraws the applicator **530** until the next matching number on a different background color barely appears out of the vagina **16**. In this manner the probe is placed at the proper distance suitable for deployment and releasable anchor in the vagina **16**. For example, the scale shown in **FIG. 11***a* is designed to deliver a positioning distance of a about 14-cm at an accuracy of about 0.5-cm. In the illustrated embodiment, the numbers from 0 to 7 are printed every 0.5-cm on the shaft **532** with their background color changing every 4-cm as shown by the color shades **542**, **544** and **546**. For example, the scale segment **542** may have a yellow background color, the scale segment **544** may have a sky-blue background color, and the scale segment **546** may have a light pink background color.

[**0126**] Another embodiment of the range adjusting applicator is shown in **FIG. 11***b*, where a range-adjuster **550** includes a ring **551** with a swivel arm **552**. Normally, the swivel arm **552** is turned toward the proximal end **533** of the applicator **530** (i.e. proximally away from the probe **500**). In a typical probe placement procedure, the probe **500** is inserted into the vagina **16** until reaching the cervix **14**. This may be done under live video guidance from the camera **506** or by the inability to further advance the probe distally.

[**0127**] The ring **551** slidably mounted on the shaft is translated along the shaft **532** of the applicator **530** until reaching the vulva **20** (i.e. vaginal opening). The applicator **530** is then slowly drawn proximally from the vagina **16** by the minimum distance necessary to allow the swivel arm **552** of the adjuster to flip distally and rest on the shaft **532**. The balloons **510** may then be inflated until a suitable view of the cervix is obtained. Finally, the release button **536** is pressed to release the probe **500** at the vaginal location attained by the foregoing process and the applicator **530** is drawn out of the vagina **16**. This procedure enables the probe **500** to be placed at a generally known distance from the cervix **14** as determined by a length **558** of the swivel arm **552** of the range-adjuster **550**.

[**0128**] Yet another embodiment of the range adjusting applicator is shown in **FIG. 11***c*, where a range-adjuster **560** includes two rings **562** and **564** tethered to each other by a tensile member or string **566** of a predetermined length. The string **566** secures the rings **562** and **564** to each other such that the rings can separate up to a distance no greater than the length **567** of the string. In that regard, one end may be tied to one ring while the other end passes through an aperture configured in the other ring as shown in **FIG. 11***c*. In a typical probe placement procedure, the probe **500** is inserted into the vagina **16** until it reaches the cervix **14**. This may be done under live video guidance from the camera **506** or by determining further distal advancement of the probe is blocked by the cervix. Both rings **562** and **564** are then slid distally along the shaft **532** of the applicator **530** until further distal movement of both rings is blocked by the vulva with tab **561** provided on the more distal ring touching the vulva **20** (i.e. vaginal opening). Then, holding the tab **561** of the adjuster against the vulva **20** with the thumb of one hand, the user grips the shaft **532** of the applicator **530** with the fingers of the other hand while resting the thumb on the tab **563** and drawing the applicator **530** proximally out of the vagina **16** up to the full length **567** of the string **566**. The balloons **510** may be then partially or fully inflated until a suitable view of the cervix **14** is obtained. Finally, the release button **536** is pressed to release the probe **500** at the vaginal location and the applicator **530** is pulled out of the vagina **16**. This procedure ensures that the probe **500** is placed at an approximately known distance from the cervix **14** as determined by a length **567** of the limiting string **566** of the range-adjuster **560**.

[**0129**] Another embodiment of the range adjusting applicator is shown in **FIG. 1** id, where a range-adjuster **570** is automatic and requires minimum effort from the user. The range-adjuster has a sliding ring **572** with a pivotable tab **574** controlling a spring-loaded locking pin **576** that rides in a longitudinal groove **578** in a shaft **580** and is adapted to lock against a toothed release-rod **582** generally co-axial with the shaft The release rod **582** is normally retracted into the shaft **580** by a spring **584** such that its distal tip **583** sits inside the shaft **580** by a distance **586** as shown. A distance **586** is

equivalent to the desired range at which the probe should be released from the applicator **530**.

[**0130**] In a typical probe placement procedure, the probe **500** is inserted into the vagina **16** until reaching the cervix **14**. This may be done under live video guidance from the camera **506** or by determining that further distal advancement of the probe is blocked by the cervix. The ring **572** is then proximally slid along the shaft **580** of the applicator toward the vulva **20** until the tab **574** touches the vulva **20**. Holding the tab **574** of the adjuster against the vulva **20**, the user simply pulls proximally the proximal end **585** of the shaft **580**. This action retracts the probe **500** out of the vagina **16** to a predetermined distance **586** where the release-rod **582** starts pushing against the probe **500** to release it from the applicator **530** and into the vagina **16**. This procedure generally enables the probe **500** to be placed at an approximately known distance from the cervix **14** as determined by the distance **586** between the distal tip **584** of the toothed release-rod **582** and the distal end of the shaft **580**.

[**0131**] Each embodiment of the range adjusting applicators described above assists the user in locating the desired distance from the cervix at which the probe is to be deployed. However, for even greater accuracy, the cervix probe **500** may include a range finder to measure the distance between the probe **500** and the cervix **14**. Knowing the magnification of the lens **504**, the measured distance may be used to convert the cervix image captured by the camera **506** to real physical dimensions (i.e. cm). The range finder may be of the ultrasonic, laser, or optical type.

[**0132**] **FIG. 12** illustrates one embodiment of the probe **500** having a range finder where a light source **602** and the camera **506** may be used for measuring the range and/or orientation of the probe. The light source **602** is configured to produce high-intensity light that passes thought a hole **604** to emerge as a beam **608** that may have a conical shape **606** with a known spread rate. The projection of the beam **608** on the cervix **14** appears as a bright spot **610** on the cervix that may be imaged by the camera **506**. The image of the bright spot **610** may be analyzed by the processor **300** to quantify the area and shape of the bright spot **610** using image-processing algorithms such as segmentation or blob analysis. The size of the bright spot **619** is indicative of the distance between the probe **500** and the cervix **14**, while the shape (i.e. circular or elliptical) of the bright spot **619** is indicative of the relative orientation or angle between the probe **500** and the cervix **14**. The processor **300** then converts the quantified area and shape of the bright spot **610** to distance and tilt between the probe **500** and the cervix **14**.

[**0133**] A second light source **612** emits diffuse light **614** to illuminate the cervix **14** and allow its proper imaging by the probe. The image of the cervix is analyzed as described above using segmentation and blob analysis to identify and measure the opening **12** of the cervix **14**. In a typical cervix measurement sequence, the first light source **602** may be illuminated momentarily whereby an image of the bright spot is captured by the camera and analyzed for size and shape to estimate the range and relative orientation of the probe **500** to the cervix **14**. After estimating the range, the second light source **612** is illuminated to provide diffuse light **614** for imaging of the cervix **14**.

[**0134**] Alternatively, a dual intensity or dual color single light source may be used instead of the two light sources **602** and **612** described above. One intensity level may be used for ranging while the other may be used for imaging.

[**0135**] Another embodiment of the probe **500** shown in **FIG. 13***a* includes a short spacer rod **620** protruding distally from the front shield **512** of the probe **500**. A distal tip **626** of the spacer rod **620** includes a reflectance oximetry sensor **622**. The spacer rod **620** may include a linear scale **624** or light reflective marks (not shown). The spacer rod **620** is sized so that it does not adversely obstruct the field of view of the wide-angle lens **504** and merely appears as a small spot in the image acquired by the camera **506**. The linear scale **624** or light reflective marks are imaged by the camera **506** along with the cervix **14** and image processing may be used to determine an insertion depth of the spacer rod **620** into the cervix opening by counting the visible tics or marks. The tip **626** of the spacer rod **620** is made of a soft rubbery material, preferably silicone, so that it rests relatively softly on a presenting part of a fetus's head **626**. The spacer rod **620** may be also configured to buckle or bend under a low compression threshold as an additional safety measure.

[**0136**] In a normal application, the probe **500** is attached to an applicator **530** and inserted under live video guidance from the camera **506** such that the spacer rod **620** is inserted into the opening **12** of the cervix **14**. Inflation of the balloon **510** may slightly push the probe **500** toward the cervix **14** such that the tip **626** of the spacer rod **620** gently rests on the presenting portion of the fetus head **628** as shown in **FIG. 13***b*. Provided that the amniotic sac has been ruptured and the mucus plug has already dropped and, the oximetry sensors **622** have good contact with the presenting portion of a fetus head **628**, the oximetry sensors **622** can measure oxygenation level of the fetus. The overall conical shape of the probe **500** may gently push the probe **500** toward the cervix **14** thereby enhancing the contact of the oximetry sensors **622** and the presenting portion of the fetus head **628**. In addition to carrying the oximetry sensor, the spacer rod **620** may help maintain the probe **500** at an approximately fixed range from the cervix **14** and hence acts as self-ranging feature.

[**0137**] In addition, to the above advantages of the spacer rod **620**, the linear scale **624** may be used to measure the length of the cervical canal. Aside from its application during labor, this probe embodiment may be used during routine clinical visits to assess the possibility of preterm labor.

[**0138**] Although the above detailed description describes and illustrates various preferred embodiments, the invention is not so limited. Many modifications and variations will now occur to persons skilled in the art. As such, the preceding description has been presented with reference to presently preferred embodiments of the invention. Workers skilled in the art and technology to which this invention pertains will appreciate that alterations and changes in the described structure may be practiced without meaningfully departing from the principal, spirit and scope of this invention.

[**0139**] Accordingly, the foregoing description should not be read as pertaining only to the precise structures described and illustrated in the accompanying drawings, but rather should be read consistent with and as support to the following claims which are to have their fullest and fair scope.

What is claimed is:

**1**. A system for monitoring dilation of a cervix opening during labor, comprising:

a probe configured to image the cervix opening and provide image data, and

a monitoring unit having a processor and an image display, the processor configured to receive and process the image data to identify the cervix opening and provide data signals representing the cervix opening to the image display for displaying information based on said data signals.

**2**. A system of claim 1, wherein said data signals include data representing a dimension of the cervix opening.

**3**. A system of claim 1, wherein the information displayed on the image display includes a graphic image of the cervix opening.

**4**. A system of claim 1, wherein the information displayed on the image display includes alphanumeric symbols indicating a diameter of the cervix opening.

**5**. A probe positionable in a vagina for monitoring a cervix during labor, comprising:

a housing adapted for insertion and withdraw from the vagina;

a camera situated in the housing, the camera adapted to capture images of the cervix;

a light source adapted to illuminate the cervix; and

a balloon on the housing, the balloon adapted to inflate around at least a portion of the housing for positioning the probe in the vagina.

**6**. A probe of claim 5, wherein the housing is configured with a distal end and a proximal end, and the camera is situated a predetermined distance from the distal end of the housing.

**7**. A probe of claim 6, wherein the probe has a distal end configured to contact the cervix opening when said balloon is inflated.

**8**. A probe of claim 7, wherein the balloon is configured such that when it is inflated the camera is positioned a predetermined distance from the cervix.

**9**. A probe of claim 5, further comprising a lens adapted to provide the camera with a wide field of view.

**10**. A probe of claim 5, further comprising a range detection means for detecting a range between the probe and the cervix.

**11**. A probe of claim 5, wherein the balloon assumes a generally conical shape when inflated.

**12**. A probe of claim 5, wherein the balloon assumes a generally spherical shape when inflated.

**13**. A probe of claim 5, further comprising a handle extending proximally from a proximal end of the housing, the handle configured to facilitate insertion and withdrawal of the probe from the vagina.

**14**. A probe of claim 12, wherein the handle is a generally flexible structure but adapted to receive a generally rigid member when used to insert the housing into the vagina.

**15**. A probe of claim 12, wherein the handle is a flexible tube having a lumen extending therethrough.

**16**. A probe of claim 13, wherein a conduit extends longitudinally along the flexible tube, the conduit configured to pass air into and out of the balloon.

**17**. A probe of claim 13, wherein the flexible tube is configured with apertures to collect fluids into the tube lumen for drainage out of the vagina.

**18**. A system for monitoring dilation of an opening of a cervix, comprising:

a probe configured to image the cervix opening and provide image data, and

a processor configured to receive and process the image data to identify the opening of the cervix and provide data on a dimension of the opening.

**19**. A system of claim 18, wherein the processor is configured to implement blob analysis to identify the opening of the cervix and measure its diameter.

**20**. A system of claim 18, wherein the processor is configured to implement image segmentation to identify the opening of the cervix and measure its area.

**21**. A system of claim 20, wherein the processor is configured to convert the area of the cervix opening into a diameter.

**22**. A system of claim 20, wherein the processor is configured to convert the area of the cervix opening into a diameter by assuming a circular cervix opening model.

**23**. A system of claim 18, wherein the dimension is a diameter and the processor is configured to implement consecutive diameter measurements to calculate a dilation rate of the cervix opening.

**24**. A system of claim 18, further comprising an image display that is controlled by the processor, wherein the processor provides to the image display signals for simultaneously displaying images of the cervix at different dilation stages.

**25**. A system of claim 18, further comprising an image display that is controlled by the processor, wherein the processor provides to the image display signals for simultaneously displaying images of the cervix opening periodically acquired during labor.

**26**. A system of claim 18, wherein the processor is configured to correct image distortion.

**27**. A system of claim 26, wherein the image distortion is caused by a lens with uneven magnification between its edges and its center.

**28**. A system of claim 26, wherein the image distortion is a barrel distortion.

**29**. A method for monitoring dilation of a cervix opening using a probe, a processor and an image display, comprising:

the probe capturing an image of the cervix opening and providing image data;

the processor receiving and processing the image data to identify the cervix opening, determining a diameter and providing data signals representing the cervix opening to the image display; and

the image display displaying information based on said data signals.

**30**. A method of claim 29, wherein the processor implements blob analysis to identify the cervix opening and measure a diameter.

**31**. A method of claim 29, wherein the processor implements image segmentation to identify the cervix opening and measure its area.

**32**. A method of claim 31, wherein the processor converts the area of the cervix opening into a diameter.

**33**. A method of claim 31 wherein the processor converts the area of the cervix opening into a diameter by assuming a circular cervix opening model.

**34**. A method of claim 29, wherein the processor implements consecutive diameter measurements to calculate a dilation rate of the cervix opening.

**35**. A probe positionable in a vagina for imaging an opening of a cervix during labor, comprising:

a housing configured for insertion into and removal from the vagina;

a camera situated in the housing, the camera adapted to capture images of the opening of the cervix;

a spacer for positioning the probe within the vagina a predetermined distance from the cervix.

**36**. A monitor of claim 35, wherein the spacer is a flexible rod extending distally from a distal end of the housing.

**37**. A monitor of claim 35, wherein the spacer is inflatable.

**38**. A probe for imaging a cervix, comprising:

an imaging member adapted to capture an image of the cervix; and

a cap covering at least a portion of the imaging member, the cap being releasably coupled to the imaging portion for disposal after use with the imaging member.

**39**. A probe of claim 38, wherein the cap includes a balloon.

**40**. A probe of claim 38, wherein a portion of the cap is transparent.

**41**. A probe of claim 40, wherein the cap includes a protective sheath that is adapted for deployment over the imaging member.

**42**. A system for monitoring dilation of a cervix opening, comprising:

a probe adapted for imaging the cervix opening and generating image data, and

a processor receiving and processing the image data,

wherein the probe has a hydrophobic imaging window.

**43**. A system for monitoring dilation of a cervix opening, comprising:

a probe adapted for imaging the cervix opening, and generating image data; and

a processor receiving and processing the image data;

wherein the probe has a hydrophobic imaging aperture.

**44**. A system for monitoring dilation of a cervix opening, comprising:

a probe adapted for imaging the cervix opening and generating image data; and a processor receiving and processing the image data;

wherein the probe has a hydrophobic probe housing.

**45**. A system for monitoring dilation of a cervix opening, comprising:

a probe adapted for imaging the cervix opening and generating image data; and

a processor receiving and processing the image data;

wherein said probe includes pneumatic means for cleaning its imaging window.

**46**. A system of claim 45, wherein the processor activates said pneumatic means based on the image data.

**47**. A probe positionable in a vagina for monitoring dilation of a cervix opening, comprising:

a housing adapted for insertion and removal from the vagina;

a camera adapted for imaging the cervix opening; and

a balloon configured to inflate for widening the vagina to provide the camera with a view of the cervix opening.

**48**. A probe of claim 47, wherein said balloon is transparent;

**49**. A probe of claim 47, wherein said balloon generally encapsulates the housing.

**50**. A probe of claim 47, wherein said balloon is multi-compartmental;

**51**. A probe of claim 47, wherein expansion of said balloon when inflated is limited by cords;

**52**. A probe positionable in a vagina for monitoring dilation of a cervix opening, comprising:

a housing adapted for insertion and removal from the vagina;

a camera adapted for imaging the cervix opening; and

a plurality of balloons disposed around said housing;

wherein inflation of said balloons widens the vagina to provide the camera with a view of the cervix opening.

**53**. A probe of claim 52, wherein said balloons are elongated along a longitudinal axis of the housing.

**54**. A probe positionable in a vagina for monitoring dilation of a cervix opening, comprising:

a housing adapted for insertion and removal from the vagina;

a camera adapted for imaging the cervix opening; and

a plurality of balloons disposed around said housing;

wherein inflation of said balloons creates channels to allow fluid drainage along a longitudinal axis of said probe.

**55**. A probe positionable in a vagina for monitoring dilation of a cervix opening, comprising:

a housing adapted for insertion and removal from the vagina;

a camera adapted for imaging the cervix opening; and

a multi-compartmental balloon disposed around said housing;

wherein inflation of said balloon creates channels to allow fluid drainage along a longitudinal axis of said probe.

**56**. A probe for imaging a cervix, comprising:

a distal imaging member; and

a proximal supporting member;

wherein said distal imaging member and said proximal supporting member are releasably coupled to each other for insertion of the distal imaging member into a vagina by the proximal supporting member and release of the distal imaging member at a suitable position within the vagina.

**57**. A probe of claim 56, wherein the proximal supporting member includes means for releasing the distal imaging member.

**58**. A probe of claim 57, wherein the release means includes a longitudinally movable member.

**59**. A probe of claim 56, wherein the proximal supporting member include means for determining a distance between the distal imaging member and the cervix.

**60**. A probe for imaging a cervix comprised of:

a distal imaging member;

a proximal elongated member which is generally flexible and configured to receive a generally rigid elongated supporting member for greater rigidity when said probe is inserted into a vagina.

**61**. A unit for monitoring dilation of a cervix opening, comprising:

a probe adapted for placement in a vagina for imaging a cervix and generating image data, and

a processor configured to receive and process the image data;

wherein the probe includes an oximetry sensor to measure the oxygenation of a fetus through the cervix opening.

**62**. A unit for monitoring dilation of a cervix opening, comprising:

a probe configured for placement in a vagina for imaging a cervix and generating image data; and

a processor configured to receive and process the image data;

wherein the said probe includes an oximetry sensor that contacts a presenting part of a fetus through the cervix opening to measure oxygenation of said fetus.

**63**. A unit for imaging a cervix from inside a vagina during labor, comprising:

a probe including:

a first light source that diffusely illuminates the cervix for imaging;

a second light source that illuminates a spot on the cervix for ranging;

a distal imaging member adapted to capture images of the cervix and generate cervix image data representing the cervix and to capture at least one image of the spot and generate spot image data;

a processor configured to receive and process said cervix image data and said spot image data, wherein the spot image data is processed to indicate a distance between said probe and said cervix.

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